A Mixed-Methods Investigation of Attitudes to Chronic Obstructive Pulmonary Disease in General Practice and the Utility of Spirometry for Improving its Recognition and Management

By

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Abstract

Chronic Obstructive Pulmonary Disease (COPD) is a major cause of disability and health care utilisation in Australia. The population prevalence is estimated at around 10% but up to 80% may be unrecognised. Lack of early diagnosis reduces the opportunity for better management. Clinical practice guidelines were developed in the 1990's to improve the diagnosis and management. The recommendation in the 2003 Australian COPDX guidelines for case finding in primary care using spirometry in high-risk subjects was based on limited evidence.

A preliminary qualitative-quantitative study of the attitudes of patients with (recognised) COPD and their general practitioners (GPs) to the disease and its diagnosis identified operational and behavioural barriers to earlier diagnosis, especially lack of access and expertise in spirometry among GPs. A cluster randomised crossover study was conducted over twelve months in eight practices in Southern Tasmania offering spirometry to smokers and ex-smokers aged over 35 years. The study compared a model of opportunistic spirometry provision by visiting trained nurses (TN) with usual care (UC) where practices were provided with an electronic spirometer and spirometry training. Models were evaluated quantitatively for effectiveness, acceptability and utility in increasing the diagnosis of COPD, and qualitatively through focus groups with GPs. A longitudinal cohort of smokers was recruited in TN practices to assess the effect of feedback about normal or obstructive spirometry on smoking cessation and motivation to stop smoking using the Transtheoretical Model of stages.

Spirometry provision in the TN model resulted in significantly more spirometry of high quality and testing in a greater proportion of the eligible population than the UC model. Although the TN model enabled recognition of substantial numbers of individuals with previously unrecognised obstruction, this did not translate into increased doctor-recorded diagnosis of COPD. Better practice systems for follow up, support for GPs in interpretation and realistic funding of spirometry are needed to achieve better outcomes from increased spirometry in primary care. Feedback to smokers with normal lung function was not associated with backward shift in stage of change but feedback on the presence of lung damage was associated forward shift in stage of change when allowing for smoking exposure. The odds of backward shift with feedback on lung damage, was related to pre-existing perceptions about poor lung health.

Although spirometry is fundamental to making a diagnosis of COPD, provision through a model in primary care that delivers a high testing rate and high quality results will not increase diagnosis in the at-risk group without an effective protocol for appropriate action on results.

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List of abbreviations

AGPAL	Australia General Practice Accreditation Limited
ALF	Australian Lung Foundation
AO	Airflow obstruction
ASCED	Australian Standard Classification of Education
ATS	American Thoracic Society
BTS	British Thoracic Society
CAL	Chronic airflow limitation
CB	Chronic bronchitis
CI	Confidence interval
COAD	Chronic obstructive airways disease
COLD	Chronic obstructive lung disease
COPD	Chronic Obstructive Pulmonary Disease
COPDX	Australian guidelines for the management of Chronic Obstructive Pulmonary Disease
DALY	Disability adjusted life year
ECHRS	European Community Respiratory Health Survey
ERS	European Respiratory Society
$FEF_{25-75\%}$	Forced expiratory flow over the middle half of the FVC manoeuvre
FER	Forced expiratory ratio (FEV1/FVC)
FEV1	Forced expiratory volume in one second
FTE	Full-time equivalent
FTQ	Fagerström Tolerance Questionnaire
FVC	Forced vital capacity
GOLD	Global Initiative for Chronic Obstructive Lung Disease
GP	General Practitioner
HSI	Heaviness of Smoking Index
ICS	Inhaled corticosteroids
IQR	Interquartile range
LABA	Long-acting beta-2 agonist
MBS	Medicare Benefits Schedule
MMEF	Maximal mid-expiratory flow rate
MRC	Medical Research Council
NHLBI	National Heart, Lung and Blood Institute

NH&MRC	National Health and Medical Research Council
NICE	National Institute for Clinical Excellence
NLF	Normal lung function
NROAD	Non-reversible obstructive airways disease
NSW	New South Wales
OLF	Obstructive lung function
OR	Odds ratio
PEF	Peak expiratory flow
PYH	Pack year history
RACGP	Royal Australian College of General Practitioners
RLF	Restrictive lung function
SABA	Short-acting beta-2 agonist
SD	Standard deviation
SGRQ	St George's Hospital Respiratory Questionnaire
SOB	Short of breath
TG	Target group
TSANZ	Thoracic Society of Australia and New Zealand
TN	Trained nurse
UC	Usual care
VAS	Visual analogue scale

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Chapter One
Introduction

1.1 Background to the thesis

Chronic Obstructive Pulmonary Disease (COPD) is a major cause of disability and mortality in worldwide (1). Using data on self-reported prevalence of chronic respiratory disease in the National Health Survey 2001, COPD is estimated to affect about 3.5% of the Australian population (2). Clinical practice guidelines for COPD in Australia, the COPDX guidelines (3), define evidence-based practice in the diagnosis and management of chronic obstructive pulmonary disease (COPD). They advise consideration of the diagnosis of COPD in all smokers or ex-smokers over the age of 35 years and specify that the diagnosis of COPD rests on the demonstration of airflow limitation which is not fully reversible. Spirometry is recommended to obtain objective measurements of lung function, as clinical signs cannot accurately demonstrate the presence or assess the severity of airflow limitation.

The guidelines also emphasise the need to prevent deterioration in lung function by actively promoting smoking cessation, through advice, pharmacotherapy and behavioural techniques. There is evidence that the sooner cessation occurs the greater the benefit (4), but it is not known if demonstrating obstructive lung function changes with spirometry promotes smoking cessation.

The development of portable, reliable spirometers has made it possible for lung function testing to be performed outside specialist physiology laboratories (5). There has been an increase in ownership of spirometers in general practice but data has indicated there is low use in Australian primary care for the diagnosis of COPD compared to other countries such as the UK or the Netherlands.

This thesis reports on work that investigated the use of spirometry in primary care with particular reference to case finding for COPD, barriers to the implementation of COPD guidelines and ways these could be overcome to increase spirometry provision in general practices in Australia and the effect of spirometry results on the intentions of current smokers to cease smoking and achieve smoking cessation.

1.2 Preliminary study

A preliminary quantitative and qualitative pilot study was carried out to investigate how the diagnosis of COPD was reached in primary care, to examine general practitioners' (GPs') beliefs and understanding about COPD and patients' understanding of COPD. The conclusions from this study underpinned the design of an intervention study.

1.3 Hypotheses

The hypotheses underlying the intervention study were:

1. That in comparison with usual care, a model using trained nurses will increase the frequency and quality of spirometry performed on smokers and ex-smokers in general practice.
2. Performing spirometry on smokers and ex-smokers aged over 35 in general practice, as specified in COPDX guidelines will facilitate early identification of COPD.
3. Identification of airflow limitation in smokers will act as an incentive for smoking cessation.

1.4 Intervention study

1.4.1 Aims of the study

The aims of the study were to compare two models of spirometry provision; visiting trained nurse (TN) or usual care (UC) in a randomised, controlled crossover trial in general practice.

In the intervention practices (TN), trained nurses visited regularly to perform opportunistic spirometry in the target group of smokers and ex-smokers aged over 35 years.

In the control practices (UC), a reliable spirometer was provided for use by GPs and practice staff. GPs and practice nurses in both arms were provided with training in the performance and interpretation of spirometry. Appropriate reimbursement for testing was offered for spirometry performed on patients in the target group.

1.4.2 Evaluation of interventions

Evaluation was carried out to establish whether there were measurable differences in defined primary and secondary quantitative outcome measures between the TN and

UC models of spirometry provision. Qualitative research methods were also used to assess and explore differences and difficulties in both models of spirometry provision.

1.4.2.1 Outcomes measured in both TN and UC practices:

1. The number and demographics of general practice patients who were smokers or ex-smokers aged over 35 screened with spirometry.
2. Comparison of the number of tests and cost of spirometry performed using the "trained nurse" and "usual care" models.
3. The quality of spirometry performed and the maintenance of technical quality over time.
4. Patients' previous respiratory diagnoses, use of respiratory medications, functional limitation due to dyspnoea (MRC scale)
5. Patients' smoking history, nicotine dependence and intentions to continue smoking or quit smoking
6. GP's experiences of the "trained nurse" and "usual care" models of offering spirometry in the practice and the logistics and barriers to its use.
7. The stability of spirometer calibration during regular use.
8. The proportion of those screened who had abnormal results and the nature/severity of the abnormalities.
9. How often spirometric abnormalities were recognised and how often recognition resulted in a formal diagnosis of COPD by the general practitioner.

1.4.2.2 Additional outcomes measured in the TN intervention practices:

1. The amount of time a trained nurse spent on spirometry if screening was offered to smokers and ex-smokers within practices.
2. An assessment of the reasons why patients agreed to spirometry screening or declined it.
3. The time taken to perform spirometry.
4. Patient self-reported attitudes towards smoking and health before and after spirometry.
5. Patient self-reported intentions to stop smoking and "stage of change" before spirometry, immediately post-spirometry and at three months after spirometry.

6. Smoking rates at three months after spirometry.

1.5 Thesis structure and overview

1.5.1 Chapter 1: Introduction

This contains a description of the chapters in the thesis.

1.5.2 Chapter 2: Review of the literature

A review of the literature and research findings to date are summarised covering the prevalence and diagnosis of COPD, evidence-based guidelines in the management of COPD, the use of spirometry in COPD and the process of smoking cessation.

1.5.3 Chapter 3: Preliminary study

This presents a report on the aims, methods, results and discussion of a preliminary quantitative-qualitative study of COPD in Tasmanian general practices that informed the development of a subsequent intervention study.

1.5.4 Chapter 4: Methodology used for further studies

This presents a detailed description of the methods used in the intervention study comparing models of spirometry delivery in primary care for patients at risk of COPD and a follow-up study on the effect of giving feedback on spirometry to smokers.

1.5.5 Chapter 5: Stability of the EasyOne Spirometer

This reports on and discusses the assessment of the stability of an ultrasonic spirometer used in primary care during a comparison of spirometry delivery models.

1.5.6 Chapter 6: A comparison of models of spirometry provision in primary care for patients at risk of COPD

This chapter presents the results and discussion of the intervention study comparing a visiting trained nurse model of opportunistic spirometry provision with a model of usual care in a practice provided with a spirometer and training in spirometry. Results are reported on the frequency, quality and acceptability of spirometry, costs and GPs' experience of the models in general practice. The prevalence of airflow obstruction in the target population tested and the impact of spirometry tests on the

diagnosis of COPD are presented with results on follow up of spirometry tests, based on data extracted from practice records.

1.5.7 Chapter 7: Effect of spirometry on smoking cessation and motivation for quitting

This chapter reports on and discusses the effect of feedback to smokers undergoing opportunistic spirometry testing, in relation to the presence of a normal or abnormal result, on motivation and preparedness to cease smoking and quitting smoking.

1.5.8 Chapter 8: Summary and conclusions

A summary of results contained in this thesis both in relation to a preliminary investigation of the diagnosis and management of COPD in primary care and in relation to the aims and hypotheses tested in a subsequent intervention study. Recommendations are made for health service organisational changes that are indicated from these results and future studies that are required.

1.5.9 Bibliography

A list of all reference cited, in the order in which they first appear in the thesis.

1.5.10 Appendices

1.5.11 Publications

Includes a list of publications to date and personal presentations given that are based on the work undertaken and reported in this thesis.

Chapter 2

Review of the literature

2.1 Importance of COPD worldwide and in Australia

Chronic Obstructive Pulmonary Disease (COPD) is associated with high economic costs globally (6) and for individual countries such as Australia (7). The health burden of COPD, measured as the sum of years lost because of premature mortality and years of life lived with disability, adjusted for the severity of the disability (DALY), was the twelfth ranked overall in 1990 and is projected to increase to fifth rank worldwide by 2020 (8). However, the diagnosis and management of COPD has been hindered over many years by lack of agreement on the definition and classification of the disease (9), and hampered by a historical lack of attention to COPD in the political and health care arenas (10).

2.2 Development of a definition of COPD

Difficulties in arriving at a clear definition of COPD lie in the differentiation from other airway diseases (especially asthma), poor understanding of pathology, a lack of emphasis on the importance of smoking in the aetiology and the absence of a "gold standard" diagnostic test. Definitions given by national respiratory societies have varied in the emphasis given to lung function characteristics and other clinical features. In 1995 the American Thoracic Society guidelines defined COPD as "a disease state characterized by the presence of airflow obstruction due to chronic bronchitis or emphysema; the airflow obstruction is generally progressive, may be accompanied by airway hyper reactivity, and may be partially reversible" (11).
The 1995 European Respiratory Society guidelines gave the definition of COPD "as a disorder characterized by reduced maximum expiratory flow and slow forced emptying of the lungs; features which do not change markedly over several months. Most of the airflow limitation is slowly progressive and irreversible" (12).
The British Thoracic Society in 1997 clarified the term COPD to include emphysema, chronic bronchitis, chronic obstructive bronchitis, chronic airflow limitation (CAL), chronic airflow obstruction (CAO), chronic airways obstruction (CAO), non-reversible obstructive airways disease (NROAD), chronic obstructive airways disease (COAD), chronic obstructive lung disease (COLD) and some cases of chronic asthma. It defined COPD "as a chronic slowly progressive disorder

characterised by airflow obstruction (reduced FEV1 < 80 % predicted and FEV1/FVC ratio < 70%) that does not change markedly over several months. Most of the lung function impairment is fixed although some reversibility can be produced by bronchodilator (or other) therapy" (13).

To overcome this fragmented and somewhat inconsistent approach to the disease taken by different national respiratory groups, a consensus developed during the late 1990's that an international approach was required to ensure that the profile of the disease was raised to reflect its importance as a leading cause of death and disability (14). Thus, an international initiative was developed between the World Health Organization (WHO) and National Heart, Lung and Blood Institute (NHLBI) to form the Global Initiative for Obstructive Lung Disease (GOLD). Its goals were to increase awareness of COPD and decrease morbidity and mortality from the disease (10).

2.3 Comparison of definitions of COPD

GOLD defined COPD "as a disease state characterized by airflow limitation that is not fully reversible. The airflow limitation is usually both progressive and associated with an abnormal inflammatory response of the lungs to noxious particles or gases" (10). Specific physiological parameters on spirometry formed the basis for diagnosis. The National Institute for Clinical Excellence (NICE) in the UK published a clinical guideline for COPD in 2004, using an integrated evidence-based approach based on intensive analysis of the literature. In this, COPD was defined as "a disease characterised by airflow obstruction. The airflow obstruction is usually progressive, not fully reversible and does not change markedly over several months. The disease is predominantly caused by smoking" (15). The differentiation of COPD from asthma was based on both aetiology and lack of full reversibility, which inevitably allows for overlap.

Guidelines on the management of COPD for Australia and New Zealand, the COPDX plan, were largely based on GOLD when first published in 2003. COPD was defined as "characterised by airway inflammation and airflow limitation that is not fully reversible. It is a progressive, disabling disease with serious complications and exacerbations that are major burdens for healthcare systems" (3).

Agreement on what characterises COPD and similarities in the definition of COPD have therefore become stronger over time. The emphasis on airflow limitation, rather

than clinical symptom-based criteria, has enabled definition of diagnostic spirometry criteria to assess the prevalence of COPD, the accuracy of diagnosis and to quantify under-diagnosis.

2.4 Aetiology of COPD

The major environmental risk factor for the development of COPD is tobacco smoke (10). Smoking accelerates the age-related decline in lung function and smoking cessation is associated with slowing of this decline (16,17). However, only a minority of smokers, around 15- 20%, actually develop COPD and the concept of a continuum of "susceptibility" to cigarette smoke, open to influence by other factors has been proposed (16).

Other exposures, including occupational dust and domestic biomass exposure, are known to be associated with COPD if sufficiently prolonged (10,18).

Host factors also contribute to aetiology. Deficiency of $alpha_1$ antitrypsin is one of the most common hereditary diseases affecting Caucasians in Europe and a proportion of individuals who are deficient in $alpha_1$ antitrypsin develop emphysema (19). The $alpha_1$ antitrypsin protein is extremely pleomorphic, and around ninety variants due to DNA mutations have been recognized. The prime function of $alpha_1$ antitrypsin is to inhibit the protease, neutrophil elastase (20).

2.5 Pathology of COPD

Three overlapping sub-types of pathology in COPD are generally recognized (21). In chronic bronchitis, traditionally associated with symptoms of cough and sputum production, there is inflammation and damage to the central airways with increased mucus production (22). In emphysema, lung parenchymal damage predominates in the inflammatory process (23) with enlargement of the distal airspaces beyond the terminal bronchioles, caused by destruction of the alveolar walls. In small airways disease, inflammation results in structural abnormalities in the airways less than 2mm in diameter with mucous exudates and peribronchial fibrosis (24). There is airflow obstruction and air trapping with increase in measured volumes in all sub-types though only emphysema causes a reduction in lung diffusing capacity. No single mechanism of inflammation can account for the complex pathology in COPD and a number of mechanisms have been proposed (21).

Most research has occurred into pathogenesis of the emphysema phenotype of COPD, with investigation of lung damage by neutrophil enzymes and the oxidant damage resulting from imbalance with antioxidative influences (25). Less research has occurred on the airway component (26) although there is evidence of inflammation and remodelling. Epithelial changes, goblet cell hyperplasia and sub-epithelial mucus gland hyperplasia have been described macroscopically over many years

2.5.1 Proteases and antiproteases

The protease-antiprotease hypothesis (23), suggests that an increased protease burden is associated with functional inhibition of antiproteases. This may be due to elastase released by recruited neutrophils. In vitro studies have demonstrated that an increased number of neutrophils are present in the lungs and airway surface fluid of cigarette smokers compared with that in non-smokers (27). Induced sputum studies have confirmed greater neutrophil counts in those with airflow limitation (28) and those with accelerated loss of lung function. Higher levels of the cytokine IL-8, known to promote leukocyte recruitment (29), have been found in sputum in chronic bronchitis (30) and stable COPD (31). However evidence for inactivation of antiproteases is less convincing and studies assessing the function of $alpha_1$ antitrypsin in cigarette smoking have not been definitive (21).

Another theory has suggested that macrophages are the crucial cell and macrophage-derived proteases are responsible for lung matrix destruction (32). A model of the acute response to inhaled cigarette smoke in the mouse found that macrophages are required for smoke induced connective tissue breakdown (33). A number of mechanisms were proposed to link the place of neutrophils and macrophages in development of lung damage in COPD and it has been suggested that a likely sequence consists of macrophage activation leading to neutrophil recruitment (33).

2.5.2 Oxidative stress

In normal lungs, there is a delicate balance between the toxicity of oxidants and the protective effects of intra- and extra-cellular antioxidant defences at the airspace epithelial surface. In oxidative stress there is a shift in favour of oxidants, caused by smoke exposure and enhanced by increased numbers of neutrophils and macrophages (21). Elastin and collagen components of the lung matrix can be damaged directly by oxidants and secondarily through increased epithelial permeability.

2.5.3 Apoptosis

Recently a role for increased alveolar cell loss has been suggested in emphysema, possibly mediated via blockade of vascular endothelial growth factor (34).

2.5.4 Innate and adaptive inflammatory immune responses

The airways possess an innate defence system that normally responds to microorganisms but can be damaged by chronic cigarette smoke exposure (22). Endobronchial biopsy studies show a cellular picture that also shows a potential role for the adaptive immune system. There is an increase in CD8+ T cells throughout the airway, but in severe disease especially there may be a CD4+ allergen driven process (24). The allergen may be autologous with antigens being exposed from damaged airway tissue or from bacteria, which chronically infect the airways progressively as the COPD worsens (25).

2.6 Development of airflow obstruction in COPD

Both airway remodelling and emphysematous lung destruction resulting from these complex inflammatory processes, cause increased resistance of conducting airways (22). Emphysema causes increased compliance of the lungs. Change in either resistance or compliance is reflected in measurement of lung emptying with a time constant. Thus both cause the airflow limitation that characterises and is used to define COPD (3,10).

Tests to assess lung function are normally carried out by simple measurements made during a forced expiratory spirometric manoeuvre (35). Studies on excised lungs linking pathological changes in the lung to changes in lung function indicated that the increase in airway resistance in COPD is predominantly from the peripheral airways (36). This has been confirmed by in vivo studies in which airway resistance was measured directly in the bronchi (37,38). Histological studies of airways in lung tissue samples from patients with COPD have found a correlation between thickening of the airway wall and progression of COPD from mild to very severe when classified using the GOLD criteria (24).

The nature of lung mechanics suggests that, as narrowing first involves peripheral airways, the earliest changes in maximum flow will occur at the end of the flow-volume curve towards residual volume as this more reflects small airway calibre. The

appearance of the maximum flow-volume curve will become increasingly convex toward the volume axis as the condition progresses. Thus in early COPD the increase in peripheral airways resistance may occur without abnormalities in total airway conductance or maximal expiratory flow (35). These early changes may be demonstrated by a reduction in mid-expiratory flow and slight changes in shape of the flow-volume loop, flattening or convexity towards residual volume as described above, in spite of preservation of a normal peak expiratory flow and FVC and only a small reduction in the FEV1 and ratio of FEV1 to FVC. There appears to be a progression in the transformation of the flow-volume curve from the normal straight or slightly concave line in the descending limb to the increasingly convex shape with increasing severity of COPD (39). It has been suggested that the convex type flow-volume curve is a sensitive index of small airway function (40).

Population studies using the performance of simple measures of ventilatory capacity have shown that flow in the mid region of expiration, either flow at 50% of FVC ($FEF_{50\%}$) or average flow during the middle half of expiration ($FEF_{25-75\%}$) discriminates between those with and without chronic respiratory symptoms or disease (41) with high correlation between these two measurements. Another study in the USA, examined the agreement between the abnormal forced expiratory ratio (FER) of FEV1 to FVC used to define obstructive lung disease and other parameters of lung function (42) in a cross section of the population. They found a high concordance (78%) between abnormality on the flow-volume curve and FER among current smokers and between abnormal $FEF_{25-75\%}$ and FER (61%). Early changes in $FEF_{25-75\%}$ may predict for later full-blown COPD if smoking continues (43). Reduction in $FEF_{50\%}$ to less than 60% of predicted normal was found in 11% of smokers aged 44 to 55 years, where FEV1 was greater than 90% of predicted normal and FER greater than 88% of predicted normal, in a community study in Sweden. Of this group, that the authors called pre-COPD, 48% had symptoms of chronic bronchitis (44).

In population surveys, mean forced expiratory volume in one second (FEV1) discriminated for subjects with chronic respiratory symptoms and was lower in smokers than non-smokers (41). Both FEV1 and $FEF_{25-75\%}$ were predictors of mortality from COPD in a UK study (45)

2.7 Measurement of ventilatory function by spirometry

Spirometry is a non-invasive test of ventilatory lung function used to measure dynamic lung volumes. The ready availability of spirometry and the ease with which it can be performed using simple equipment makes it the most important test to detect, quantify and monitor diseases such as COPD that limit ventilatory capacity (46).

Spirometry is recorded as either a spirogram (a plot of volume against time) or a flow-volume curve (a plot of volume against flow). The most commonly measured indices recorded following maximal inspiration and forced expiration are:

1. Forced expiratory volume in one second (FEV1)
2. Forced vital capacity (FVC)
3. FEV1/FVC ratio or forced expiratory ratio (FER)
4. Maximal mid-expiratory flow rate (MMEF) or forced expiratory flow over the middle half of the FVC manoeuvre ($FEF_{25-75\%}$)
5. Peak expiratory flow (PEF)

2.8 Classification of abnormal spirometry

Spirometry can be classified on the basis of these major indices into three abnormal patterns (46).

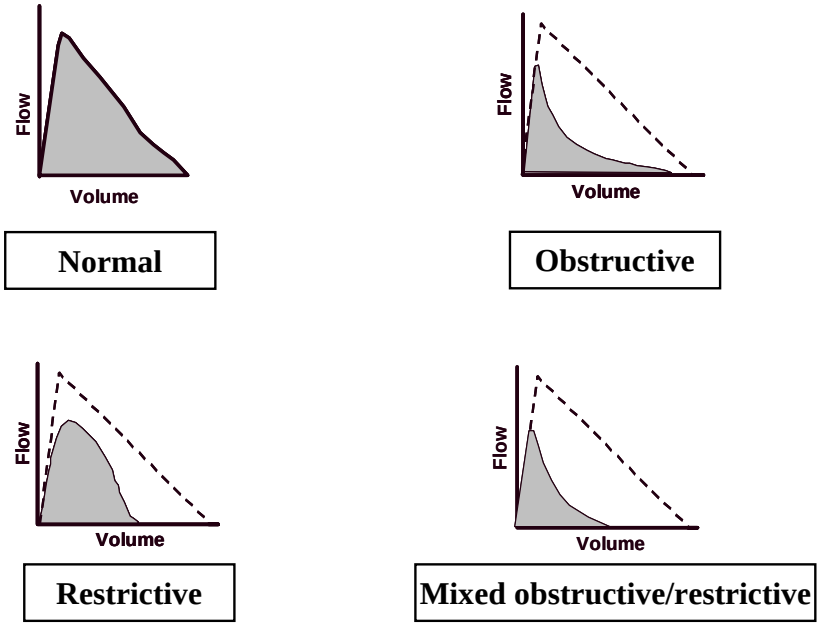
1. An obstructive ventilatory defect with reduced FEV1, FEV1/FVC ratio or PEF.
2. A restrictive pattern with loss of lung volume without airflow limitation suggested by low FVC but a normal or high FEV1/FVC ratio.
3. A mixed obstructive and restrictive pattern with airflow limitation and loss of lung volume shown by low FVC but low FEV1/FVC ratio.

The shape of the flow-volume curve may also vary between an obstructive defect, where the expiratory curve is convex towards flow and volume axes, and a restrictive disease where the shape may be concave towards the axes.

More complex tests of ventilatory function normally undertaken in a physiology laboratory setting, such as measurement of total lung capacity and residual volume, are required to confirm both the restrictive and mixed obstructive/restrictive abnormalities.

A particular confounder can exist where a high residual volume due to air-trapping causes the decrease in FVC giving the false appearance of restriction.

Figure 2.1: Expiratory flow-volume curves typical of normal ventilatory function and three classification categories of abnormal ventilatory function: obstructive, restrictive and mixed obstructive-restrictive.



2.9 Evidence-based principles for diagnosis of COPD in guidelines

Clinical guidelines have been developed for COPD to specify diagnostic and management criteria. The statements and recommendations included in guidelines developed since the late 1990s have generally been based on evidence that was assigned a specific level indicating the strength of the evidence base(47). At the time the international GOLD guidelines were developed in 1998 (10), the US National Heart, Lung and Blood Institute (NHLBI) was using a classification of evidence based on four levels:

A: Evidence from a substantial number of randomised controlled trials involving substantial numbers of participants in the population for which the recommendation is to be made, providing a rich body of data.
B: Evidence from randomised controlled trials with a limited body of data from few trials with a small number of participants, or not in the target population of interest.
C: Evidence from uncontrolled or non-randomised trials or observational studies.
D: Panel consensus judgment where the clinical literature is insufficient.
The Australian guidelines developed in 2001 by the Thoracic Society of Australia and New Zealand (TSANZ) and the Australian Lung Foundation(3) used the National Health and Medical Research Council (NH&MRC) classification of levels of evidence (48):
I: Evidence obtained from a systematic review of all relevant randomised controlled trials.
II: Evidence obtained from at least one properly designed randomised controlled trial
III-1: Evidence obtained from well-designed pseudo-randomised controlled trials
II-2: Evidence obtained from comparative studies (including systematic reviews of such studies) with concurrent controls and allocation not randomised, cohort studies, case-control studies, or interrupted time series with a control group
II-3: Evidence obtained from comparative studies with historical control, two or more single arm studies, or interrupted time series without a parallel group
IV: Evidence obtained from case series, either post-test or pretest/ post-test
The levels of evidence classified using NH&MRC categories were linked to corresponding NHLBI levels in the published guideline (3).

2.10 Spirometric and symptom criteria for the diagnosis of COPD

The use of standard classification criteria can provide a means of comparing disease prevalence in different settings. There is agreement between most international and national COPD guidelines (3,10,11,13,15,49) on the level of the FEV1/FVC ratio indicating significant airflow limitation. In most COPD guidelines the cut-off point specified for an obstructive ventilatory abnormality is a ratio of FEV1/FVC less than 0.7 (post-bronchodilator). The European Respiratory Society (ERS) criteria (12) are based on mean population reference values that take into account variation in airflow limitation according to age and gender (50). Use of these criteria reduces the likelihood of misclassification that may occur with use of a fixed FEV1/FVC ratio.

The criteria used to classify the severity of COPD vary slightly but significantly between guidelines and this can lead to some confusion in clinical practice (Table 2.1) (51).

In addition, while the major current respiratory guidelines agree on some key points covering the diagnosis of COPD (such as the level of the FEV1/FVC ratio) they vary in the interpretation of non-reversibility (52). The criteria proposed to indicate significant bronchodilator reversibility, as occurs in asthma, vary between guidelines and have varied over time (Table 2.2).

The presence of specific clinical symptoms is not included in the definition of COPD by international or Australian guidelines (3,10). A review of population studies in adults with COPD or respiratory symptoms (53) found that 23% of subjects with normal spirometry reported respiratory symptoms although the percentage of subjects reporting symptoms increased with worsening airflow obstruction. In addition, respiratory symptoms were not reported by 21% of subjects with severe airflow obstruction. Thus guidelines generally list symptoms including breathlessness, cough, sputum production, wheeze and frequent bronchitis whose presence in a patient, with or without a history of exposure to risk factors such as smoking, should prompt consideration of a diagnosis of COPD and performance of spirometry to confirm.

Table 2.1: Comparison of diagnostic classification of COPD in respiratory guidelines on the basis of symptoms or spirometry

[[1] (54), [2] (49), [3] (3), [4] (13), [5] (15), [5] (12)]

	At Risk: Stage 0	*Mild COPD*	*Moderate COPD*	*Severe COPD*	*Very Severe COPD*
GOLD 2005[1]	Lung function normal, chronic bronchitis symptoms (cough and /or sputum, usually in winter months and on most days for as long as 3 months each year).	FER < 0.7, FEV1 ≥ 80% predicted (post-bronchodilator)	FER < 0.7, FEV1 50-79% predicted (post-bronchodilator)	FER < 0.7, FEV1 30-49% predicted (post-bronchodilator)	FER < 0.7, FEV1 <30% predicted (post-bronchodilator)
ATS/ ERS 2004[2]	Smoker, occupational exposure, or symptoms of cough, sputum, dyspnoea	FER ≤0.7, FEV1 ≥80% predicted	FER ≤0.7, FEV1 50-80% predicted	FER ≤0.7, FEV1 30-50% predicted	FER ≤0.7, FEV1< 30% predicted
COPDX 2003[3]		FER < 0.7, FEV1 60-80% predicted	FER < 0.7, FEV1 40-59% predicted	FER < 0.7, FEV1 < 40% predicted	
BTS 1997[4]		FEV1/FVC < 0.7, FEV1 60-80% predicted	FEV1/FVC < 0.7, FEV1 40-59% predicted	FEV1/FVC < 0.7, FEV1 < 40% predicted	
NICE 2004[5]		FER < 0.7, FEV1 50-80% predicted	FER < 0.7, FEV1 30-49% predicted	FER < 0.7, FEV1 > 30% predicted	
ERS 1995[6]		Males FER < 88.5% predicted, Females FER <89.3% predicted, FEV1 ≥70% predicted	Males FER < 88.5% predicted, Females FER <89.3% predicted, FEV1 50-69% predicted	Males FER < 88.5% predicted, Females FER <89.3% predicted, FEV1 <505 predicted	

2.10.1 International guidelines (10)

GOLD guidelines state that the diagnosis of COPD rests on a history of exposure to risk factors and the presence of airflow limitation that is not fully reversible. The presence of cough, sputum production or dyspnoea and/or a history of exposure to risk factors are listed as factors which raise the possibility of a diagnosis of COPD, without recording the level of evidence substantiating these recommendations. The guidelines do emphasise that spirometry is the gold standard for measuring airflow limitation and that health workers involved in the diagnosis and management of COPD patients should have access to spirometry (10). No criteria for reversibility of airflow limitation after inhalation of a bronchodilator were specified in the original or updated guidelines (54) but spirometric values of FEV1 and FVC used to classify COPD were post-bronchodilator values. Post bronchodilator reversibility testing was recommended, to establish the best attainable lung function, gauge prognosis and guide treatment decisions. It was to be performed once in general, at the time of diagnosis. Although, the purpose was to rule out a diagnosis of asthma, the level of reversibility considered significant was not stated (Table 2.2).

2.10.2 UK guidelines (15)

NICE guidelines in the UK recommend that a diagnosis of COPD should be considered in patients over the age of 35 years who have a risk factor (generally smoking) and who present with one or more of the following symptoms: exertional breathlessness, chronic cough, regular sputum production, frequent winter "bronchitis", or wheeze. It is recommended that health professionals managing patients with COPD should have access to spirometry and be competent in the interpretation of the results. The evidence supporting this recommendation is only Level D (NHLBI) consisting of panel consensus judgement and the guideline points out a lack of evidence at the highest level (Level A).

Bronchodilator reversibility testing is not routinely recommended at diagnosis (Table 2.2). The lack of repeatability of FEV1 measurements and the purely arbitrary definition of the magnitude of a significant change are cited as some of the reasons for this position.

2.10.3 Australian guidelines (3)

COPDX guidelines in Australia make recommendations on diagnosis based on Level B evidence. Firstly, that the diagnosis of COPD should be considered in all smokers

and ex-smokers over the age of 35 years, and secondly that the diagnosis rests on the demonstration of airflow limitation which is not fully reversible. A list of indications for spirometry includes breathlessness, chronic cough (daily for two months), intermittent cough, frequent or unusual sputum production and relapsing acute infective bronchitis. Bronchodilator reversibility testing is recommended at diagnosis. Although one justification for this is to confirm or exclude asthma, and a significant change is defined as an increase in FEV1 of more than 12% and 200ml, the guideline notes that this is not specific to asthma. Clinical features of atopy and smoking history are suggested as the basis of differentiation.

Thus, although spirometry is widely accepted as a good tool to use in clinical practice, whether it will be used and whether it will make a difference, either positive or adverse, is untested especially in primary care.

Table 2.2: Criteria indicating significant bronchodilator reversibility on spirometry in COPD guidelines

Guideline	*Change in FEV1 15 minutes post-bronchodilator*
ERS 1995(12)	≥ 10% predicted FEV1
ATS 1995 (11)	≥ 12% and 200ml of baseline FEV1 or FVC
BTS 1997 (13)	≥ 15% of baseline FEV1
COPDX 2003 (3)	≥ 12% plus 200ml of baseline FEV1 or FVC (states this is not diagnostic of asthma and may occur in COPD)
NICE 2004 (15)	Non specified
GOLD 2004 (10)	None specified

2.11 Prevalence of COPD

2.11.1 International population prevalence surveys

Prevalence rates for COPD vary, partly due to the use of differing definitions. International prevalence rates in developed countries, when assessed by spirometry and based on the GOLD criterion for diagnosis of obstruction in COPD, give overall

rates for COPD ranging from 3.7% in Denmark (55), 4.5% in Norway (56) to 6.8% in the USA (57).

Studies that take into account age related changes in the FER, relating it to population values, such as those used in the 1995 guidelines of the ERS (12) gave higher overall prevalence estimates, 9.1% in Spain (58) and 11% in Italy (59). The latter study highlighted the variation in prevalence estimates of COPD obtained in the same population depending on the criterion used to define airways obstruction and the higher prevalence estimates that result from using an absolute value of FER. Prevalence rates derived from symptoms or self-reported diagnosis tend to be higher (60,61) than rates based on spirometric assessment (9).

Prevalence rates are lower when based on a younger population, such as that studied with European Community Respiratory Health Survey (ECRHS) (62) in sixteen countries worldwide (63). In 20-44 year olds (including symptomatic subjects and a random sub-sample of non-symptomatic subjects), the overall prevalence of COPD was 3.6%. The prevalence of mild COPD was 2.5% and prevalence of moderate or severe COPD was 1.1%. Stage 0 or “at risk” of COPD based on the presence of symptoms and normal spirometry, introduced in an updated version of GOLD in 2004, was found in 11.8% of subjects.

In response to the lack of consistently and accurately determined prevalence estimates for COPD, an international Burden of Lung Disease (BOLD) initiative has been established (64). The aim is to conduct prevalence surveys among adults aged over 40 in multiple sites around the world including in Australia. In addition to prevalence rates, the survey will document the impact of COPD with regard to disability, impaired quality of life and health care costs and provide a better basis for projecting the economic and social burden in the future.

2.11.2 Australian prevalence of COPD

Estimates of COPD prevalence in Australia depend on the population studied and the definition used. This is well illustrated in a two-stage cross-sectional epidemiological study conducted in Melbourne, using the ECRHS methodology (62). In adults aged between 45 and 69 years (n= 7,005) the self-reported prevalence of emphysema was 1.2%, with the diagnosis confirmed by a doctor in 96% cases (60). However, in a random sub-sample of 40% subjects, evidence of COPD (impaired gas diffusion and/or FEV1/FVC < 0.75) was found in 12.1% (65). Respiratory symptoms were common with cough and sputum production reported by 12.5% subjects. The

prevalence of COPD, estimated in a longitudinal population study of adults aged over 18 years in South Australia, varied depending on the criteria used: ATS, 5.4%; BTS, 3.5%; ERS, 5.0%; GOLD, 5.4% (66).

2.12 Under-recognition of COPD

2.12.1 Level of under-diagnosis

All community prevalence surveys have found that the majority (40-78%) of those with airflow obstruction on testing had no previous or current diagnosis of an obstructive lung disease (57,58,67-69). Similar levels of under-diagnosis are found in general practice (70-72) but no major improvement in recognition has occurred despite increased availability of spirometry over three decades (73). A survey carried out in the Netherlands in 1992, compared the prevalence of asthma and COPD with that in 1977 in ten general practices, and the level of recognition by general practitioners (72). National criteria at the time of the survey used a grading system based on both symptoms and the level of FEV1 compared to predicted values, divided into five grades of severity. Absence of asthma or COPD was based on no respiratory symptoms (chronic cough, chronic expectoration, dyspnoea, wheezing, asthma attacks or episodes of bronchitis) and FEV1 above 95% predicted value. The prevalence of grades 1-5 of asthma/COPD was 30.6% compared to 19.0% in 1977 in a survey in the same region. The proportion unknown to the GP in 1977 was 77% compared to 65% in 1992. In 1992, 93% of those graded with more severe disease had already been diagnosed but under-recognition was more likely in lower severity grades. 70% of those with symptoms and FEV1 >95% predicted or FEV1 85-95% predicted were un-diagnosed.

2.12.2 Reasons for under-diagnosis

Reliance on clinical symptoms and signs contributes to this under-recognition. An evidence-based review of diagnostic studies commissioned in the US reported that physical signs, such as wheezing or rhonchi on clinical examination, all have high specificity (>90%) but low sensitivity for airflow limitation (53). In the US National Health and Nutrition Examination Survey conducted between 1988-1994, respiratory symptoms were reported by 23% of individuals with normal spirometry while 21 % of individuals with severe to very severe airflow obstruction (FEV1 < 50 % predicted) had no symptoms (57).

Another contributory factor is non-presentation of symptoms to GPs. Despite the presence of significant respiratory symptoms assessed as “severe” in the participants in the study by Tirimanna et al (72), only 27% had ever consulted their GP for their symptoms (74).

Increased age does not seem to be associated with under-diagnosis (75) and there is evidence from a study by Vandevoorde et al in Belgian general practices that under-diagnosis was more frequent in younger patients (76). The same study found that having a chronic cough and the presence of fatigue were independent predictors of having a diagnosis of COPD compared to being unrecognised.

2.12.3 Consequences of non-recognition of airflow limitation

Among those with undiagnosed airflow obstruction, airflow limitation measured as decreased FEV1 % predicted is an independent predictor of mortality (45,77) and is independently associated with impaired health and functional status (78). In addition, impaired pulmonary function has been found to have a significant association with subsequent impairment of quality of life. In a population survey of middle-aged adults between 1983-1984 in urban and rural China, FEV1 was significantly correlated with scores for general, independence, physical, psychological, and environmental domains and total quality of life when measured nine years later (79). Only about 10% of the association was explained by smoking and 50% by respiratory symptoms. Decline in quality of life was more rapid as FEV1 declined below a level of 80% predicted.

However if airflow limitation is not recognised, there is less opportunity to offer effective intervention and potentially prevent further impairment of pulmonary function. Thus detection and monitoring of patients with airflow limitation has become accepted as desirable clinical practice in primary care (80,81) but this has never been formally tested in clinical primary care practice.

2.13 Case finding in COPD

Case finding for COPD is defined as screening by spirometry in “patients who seek medical care for unrelated symptoms and who are at high risk for COPD due to a history of heavy cigarette smoking” (5). This targeting differentiates case finding from spirometry screening in unselected populations, in which the requirements for effective screening are not met (82,83). The use of spirometry for case finding in

COPD remains an area of controversy (84,85). On the evidence available in 2005, case finding was not recommended in a report prepared for the US Government on two grounds; because of lack of effectiveness for spirometry on smoking cessation and lack of availability of effective therapy in airflow obstruction in the absence of symptoms (53). However, case finding has been assessed as relatively cost effective (86). There is however considerable evidence for the feasibility of spirometry in case finding and this is presented in the following sections.

2.13.1 International experience of spirometry screening

A study carried out in 33 general practices and 23 hospital clinics in Japan found undiagnosed airway obstruction by GOLD criteria (Table 2.1) in 281 (27%) of 1,040 subjects considered to be at high risk of COPD (smokers or ex-smokers) (87). Post-spirometry, doctors provided a diagnosis for 70% of those with airway obstruction, asthma in 13% and COPD in 81% (39% classified as mild, 38% as moderate and 19% as severe). Results did not differentiate between GPs and hospital-based physicians.

In a primary care setting in Belgium, 19% of patients who had smoked for at least 10 pack years and were consulting for a non-respiratory complaint without a prior respiratory diagnosis, demonstrated airflow limitation on spirometry by GOLD criteria (Table 2.1). Classification of severity of airflow obstruction was: mild in 34%, moderate in 52% and severe in 14% (88). Another study in Belgium surveyed 3,408 patients between 35 to 70 years consulting a GP over a three-month period (89). 250 patients with known obstructive lung disease, based on current use of bronchodilators were excluded. Among 703 patients with at least one current or recent respiratory symptom tested with spirometry, 18% showed obstructive lung disease using ERS criteria (Table 2.1) and among a random sample of 222 asymptomatic patients, 4% showed obstructive lung disease using ERS criteria. Overall, an estimate of 216 new cases of obstructive lung disease in this population visiting their GP for any reason was made, of whom 42% would not have been recognised on symptom enquiry alone. Although this study was not designed as a prevalence survey, the results would be consistent with a prevalence of 3-5% overall, lower than rates found when smokers are targeted.

A community-based study in a single region in Sweden targeted smokers aged 40 to 55 years. The eligible population was estimated as 19,750 smokers (44). Spirometry was performed on participants recruited in primary health care centres using posters

by trained, experienced nurses. It was repeated with bronchodilator reversibility testing and a steroid reversibility test in those with obstructive lung function. Of 512 smokers tested, 147 (28.7%) had obstructive lung function using the ERS criteria (Table 2.1). Among these smokers with airflow obstruction, a diagnosis of COPD was made in 96% (classified as mild in 85%, moderate in 13% and severe in 3%) and a diagnosis of asthma in 4%. This was not a population prevalence study and those who responded to the invitation for spirometry had more symptoms than smokers in general. Thus the prevalence of COPD of 27% in this sample of smokers overestimates the frequency of COPD in the total population of smokers.

2.13.2 Australian experience of spirometry screening in general practice

In population of smokers aged over 40 years with at least 10 pack years smoking history in a rural and a suburban practice (n= 355), the prevalence of airway obstruction was 40% using GOLD criteria (90). Severity of obstruction was classified as mild in 28%, moderate in 8% and severe in 4%. Only 7% of those with obstruction on spirometry had a prior diagnosis of COPD.

2.13.3 Presentation in general practice with symptoms of COPD

Shortness of breath is specified in the GOLD guidelines as a key indicator for prompting consideration of a diagnosis of COPD (10). Breathlessness was given as a reason for the encounter with a GP in 0.9 per 100 encounters in Australia between 1998 and 2004 (91) in a continuous survey in primary care (92). This would equate to 900,000 encounters per year across Australia. It was the sole reason for 33.8% of these encounters. Where there was no diagnosis, the most frequent investigation was chest radiology (38.2%) with referral for respiratory specialist advice occurring in 2.5%. Of those whose reason for the encounter was a chest symptom or complaint (other than asthma), only 11.2% had a non-radiological investigation, generally spirometry.

2.13.4 Misclassification of COPD in general practice

Case finding requires spirometry and unless a diagnosis is based on spirometry, COPD may be misclassified (93,94). A study in three practices in the UK that did not own a spirometer, used spirometry with bronchodilator reversibility testing to investigate patients on an asthma register. Results showed that 34% actually had COPD using a definition of FEV1< 75% predicted and bronchodilator reversibility <

15% and <200 ml (95). Another study in the UK recruited patients in one practice with a recorded diagnosis of asthma or COPD. These patients underwent spirometry which was assessed by the GP and two specialist physicians. There was a high level of disagreement between the diagnosis recorded and the GP diagnosis based on spirometry (96). Reasons for misclassification other than lack of spirometry or incorrect interpretation could include evaluation of clinical context such as age, sex and smoking status (96,97) and socio-economic factors (97). Similarly high rates of misclassification are likely in Australia, although no data are available.

2.14 Current use of spirometry in the diagnosis of COPD in general practice

There is good evidence that despite recommendations in guidelines, the majority of diagnoses of COPD made in general practice are made without spirometry demonstrating the presence of airflow obstruction.

2.14.1 International evidence

A study in the US published in 2005, examined a national electronic database for use of pulmonary function tests and recording of risk factors such as smoking status in 35,957 cases of newly diagnosed COPD (98). Fewer than 2% had pulmonary function tests carried out prior to diagnosis and fewer than 3% even after diagnosis. Another study in the US in 1999 examined the use of spirometry in a cohort of newly diagnosed patients with COPD aged over 40 in the Veterans Healthcare system and found that 66.3% had not had spirometry (99).

In the UK, the computer-linked records of patients of 360 GPs in 100 nationally distributed practices were analysed in 2000. Spirometry had been performed in 10% of patients before or within three months of diagnosis while overall less than 20% of patients with COPD had ever had spirometry (100). When practice diagnosis was compared to spirometry performed following completion of a respiratory screening questionnaire in the UK in a sample of 336 patients, the GP diagnosis agreed with the spirometry label in 41 out of 96 cases (42.7%). Furthermore, for the 71 patients with COPD by spirometry criteria, only 20 (28%) patients had a recorded diagnosis of COPD while 13 (18%) patients had a sole diagnosis of asthma (68).

2.14.2 Australian evidence

There are few practice-based data on spirometry use available from Australian primary care practices. In a survey of spirometer ownership and usage in 2004, 89.5% of general practices that owned a spirometer stated that they used it to diagnose asthma, 77.7% to diagnose other respiratory diseases such as COPD and 39.2% to screen smokers and ex-smokers. However no data were collected on the frequency of spirometer use in each condition (101).

The Australian government publishes data collected by Medicare on the number of items in the Medicare Benefits Schedule (MBS) (102) claimed for reimbursement. The item relating to measurement of respiratory function by spirometry performed before and after bronchodilator (Item number 11506) attracted a fee of $ AUS 17.75 in 2005. In the year from July 2005 to June 2006, a total of 244,875 claims were made of which 174,004 claims (71%) were made by GPs, at a cost to the Australian Government of $AUS 2,623,727. Claims for patients aged over 35 years accounted for 73% of the total (103). In the Southern Tasmanian Division, 1,363 tests were claimed by GPs in 94 practices, i.e. an average of 14.5 tests per practice annually, only just over one a month.

There is considerable variation between states in the rate of spirometry per 100,000 of population performed under Medicare item number 11506, from 1,640 in Queensland and 1,597 in New South Wales to 897 in Tasmania and 495 in Victoria with an average of 1,189. Expressing the rate of spirometry crudely as a percentage of the Australian population, around 1% of Australians over 14 years of age had spirometry performed in general practice in one year.

No Medicare benefit item for spirometry without bronchodilator reversibility testing had been introduced during the time period covered by these data, so these figures do not include single occasion spirometry tests that may have been performed to monitor known COPD.

2.15 Factors affecting use of spirometry in general practice

Successful use of spirometry to diagnose COPD in general practice depends on a number of factors, including ownership of spirometers, training in spirometry (the ability to perform accurate and reliable testing and the ability to interpret the results), using spirometry on those at risk of developing COPD, economic factors (equipment cost, payment for testing) and patient willingness to be tested.

2.15.1 Ownership of spirometers

Ownership of spirometers in general practice has been rising. Rates increased from 50% in 1998 to 69% in 1999 in a survey of 209 GPs in the UK (104). In a survey of general practice practices in Wales in 2003, 304/371 (82%) owned a spirometer (105). All general practices throughout Australia (5,976) were surveyed in 2004, and among 1,125 practices (19.5%) that responded, spirometer ownership was found in 722 (64.2%) (101). Over estimation by responder bias did not appear to explain the high level of ownership. In a survey of 160 of initially non-responding practices, with 74% response rate, 83.9% owned a spirometer.

The National Lung Health Education Program in 2000 recommended development of a new type of spirometer suitable for use in the primary care setting. Important factors for primary care were cost, size, ease of use and quality assurance (5). In Australia a national Commonwealth Government initiative to assist GPs to choose a spirometer that best meets these criteria, led to the development of a buyers' guide to spirometers, available in print and via the internet (106).

2.15.2 Performance of spirometry

Spirometry is an effort-dependent test and the ability of the subject to produce a valid, repeatable result is related to the competence of the test operator to coach effectively and identify problems (46). Recent surveys have indicated that the operator of spirometers in general practice is generally either a practice nurse or GP. In Australia, in 64% of practices nurses performed spirometry, and in 58% of practices GPs performed spirometry (101). In the UK, spirometry was usually carried out by a nurse in 69% of practices, by a GP in 9% of practices and by either a nurse or GP in 11% of practices (105). Other personnel such as practice assistants (107,108) and pharmacists (109) also perform spirometry in general practice or in the more general community setting.

2.15.3 Time required for testing

Spirometry has been shown to be feasible in the context of surgery attendance for other reasons, taking an average time of 17 minutes with minimal disruption of normal surgery activity in a UK study (110).

A study using trained non-medical personnel in the Netherlands reported a mean time of 4 minutes (SD 1.1) for performing three tests of FEV1 (80) while a study of

GPs in Italy (111) reported a median time of 6 minutes for execution of the spirometry test and 5 minutes for instructing the patient. The Dutch study did not require complete expiration and measurement of FVC, which may explain the shorter time found in that study.

2.15.4 Training

Training in performance of spirometry increases the quality of spirometry performed by GPs. After training, 33% of tests in a period of twelve weeks showed at least two acceptable blows compared to 13% when done by GPs without training (112). The amount and source of spirometry training reported by those carrying out tests varies widely. In a UK survey in 1999, 93% of practice nurses had received training; 69% by a recognised training body, 46% by a pharmaceutical company representative and 21% by equipment manufacturers (104). In Australia, training was received either from a recognised training body or from another source by about half of the practices surveyed in 2004 (101). The length of training reported in the Australian study was less than two hours by 40% of practices and a half-day by 24% of practices. In Wales, the median length of training was reported by practices as two hours. There was a significant, positive association between length of training and reported confidence in interpreting results (105). With five hours of training the quality of spirometric tests in general practice has been found to be equivalent to that of a pulmonary function laboratory (107). The proportion of non-reproducible tests (FEV1 reproducibility $\geq$ 5% or > 200ml) was 16% for practice assistants and GPs and 18% in laboratories. There was considerable variation in the proportion of non-reproducible tests between practices, varying from 4% to 35% while laboratories ranged from 13% to 20%.

2.15.5 Spirometer calibration

The accuracy of testing is affected by the calibration of the spirometer. Calibration is the procedure for establishing the relationship between sensor-determined values of flow or volume and the actual flow or volume (113). Most spirometers suitable for use in primary care automatically adjust the accuracy of the spirometer after calibration, though in some cases the adjustment can only be carried out by the distributor or manufacturer (106).

Recommendations updated in 2005 in a joint report by American Thoracic Society and European Respiratory Society, state that the calibration of a spirometer should be

checked daily with a 3-litre calibration syringe and periodic testing with a biological control should be carried out to check the stability of the instrument (113). In practice, calibration accuracy checks are rarely performed in primary care (101,114). Only 22% of practices surveyed in Australia ever used a calibration syringe and fewer than 2% carried out daily checks (101). As stated earlier, the National Lung Health Education Program in the US recommended developing alternatives to remove the need for this requirement (5).

2.15.6 Spirometer design

Spirometers meeting recommendations for suitability for use in primary care should be of lower cost, smaller in size, easier to use, easier to have calibration checks performed and have good quality assurance features (5). Further, monitoring quality electronically and displaying specific messages when errors are detected, assists the operator to obtain high quality spirometry.

In primary care, spirometer reliability and ease of maintenance are considered particularly important equipment features (106). The use of ultrasonic technology to measure airflow in a spirometer designed without moving parts is one way of eliminating inaccuracy due to instrument errors inherent in some other operating systems. An example is the EasyOne™ (ndd Medizintecknik AG Technoparkstrasse, Switzerland), a handheld spirometer that should in theory maintain its accuracy throughout its operational life.

2.15.7 Influencing spirometry use in clinical practice

Despite the development of evidence-based guidelines for clinicians, it is known that spirometry uptake and implementation remains low in many conditions including COPD (115,116). A number of reasons may be contributing at levels other than those of practitioner knowledge and skills, including barriers due to structural, operational, peer-group and communication difficulties. Such barriers may be addressed through educational interventions, audit and feedback and reminders (117). An educational intervention in Canada was shown to increase the appropriate use of spirometry in general practice to 37%, almost doubling the pre-intervention rate of 20% (118). However under-use and variation in use of spirometry, compared with guideline-specified indications, persisted in a Dutch study of GPs and practice assistants in practices equipped with spirometers fourteen months after extensive spirometry training (119).

2.15.8 Cost effectiveness of spirometry

A cost effectiveness study in the UK, using data from one study in the Netherlands (108) calculated that the cost per life year gained from using spirometry opportunistically for case finding was £713.16 and the cost per quality adjusted life year gained was £816.56 (15,86). This is a good cost effectiveness ratio compared to other screening programmes (120). The cost per case of COPD or asthma detected in a screening programme in general practice in the Netherlands, involving symptom enquiry and lung function measurement, was much lower than that of screening for hypercholesterolaemia, prostate cancer or breast cancer (121).

2.15.9 Acceptability of spirometry

There is little direct information on the acceptability of spirometry to patients. A participation refusal rate of 34% was found in a prospective European study in general practice to detect COPD and asthma, although some of the refusers agreed to participate in testing at home (121). Another practice-based case finding study in Holland had a 2.5% refusal rate but no information on the reasons for refusal was given (108). A UK study found only 2% of patients aged over 45 years refused opportunistic spirometry screening for COPD when attending for a consultation, while 20% refused home-based screening and only 33% actually had spirometry at home (110). Spirometry invitations in this study were not offered to every patient attending the practice during screening sessions. The acceptability of spirometry may depend on the reason for performing it. Thus in a practice-based study with the primary objective of investigating spirometry and smoking cessation, 31% of smokers refused to participate, though their reasons were not reported (122).

2.16 Spirometry interpretation

The use of spirometry to identify patients with COPD relies on correct interpretation of results. Most data suggest that GPs are not confident about their ability to interpret spirometry. Limited or no confidence was reported by 65% of practices in a UK survey restricted to practices in Wales (105). This is consistent with a study using hypothetical cases presented to a sample of 839 Spanish GPs in which 31% did not receive a correct diagnosis based on the spirometry result when the obstruction was moderate and 23% when obstruction was severe (123).

In a national survey of UK GPs in 1999, 78% could identify a trace and readings for severe COPD, but only 40% could identify mild COPD correctly (104). A later survey in 2002 found that 42% of GPs in the UK were not confident or not at all confident about diagnosing COPD, compared to 17% of GPs who were not confident or not at all confident about diagnosing asthma (116). This difference may be related to the greater dependence of the diagnosis of COPD on spirometry interpretation. Analysis of a random sample of spirometry results from practices in New Zealand by expert respiratory specialists found agreement with GPs' interpretation in only 53% of cases, irrespective of whether GPs had been trained in performing the test or not (112). Of the 22% of practices in Wales reporting that spirometry was always used to attain a diagnosis of COPD, 62% reported feeling confident in interpretation of spirometry (nearly twice the overall rate) (105).

The interpretation of selected spirometry results from 12 standardised case descriptions, by GPs in the Netherlands who had been trained in and were experienced in using spirometry, were compared to those of an expert panel. Concordance was found for obstructive physiology in 91.3% (95% CI 86.8 to 95.8) of cases and for normal spirometry in 77.9% (95% CI 70.2 to 85.6) of cases. The proportions were lower for incorrect manoeuvres or rare respiratory pathology (124). Negative predictive values were 0.96 for obstructive patterns and 0.93 for normal spirometry with positive predicted values of 0.87 and 0.75 respectively. The lower positive predictive values compared to negative predictive values are consistent with the lower a priori probability existing in general practice where it is more difficult to label a disease than to exclude it.

A correct diagnosis of COPD is also affected by the attitudes held by GPs. A study in Spain found that males were more likely to be diagnosed with COPD than women, even with the same history, smoking consumption, physical findings and degree of obstruction on spirometry testing (123). There is currently little known about any other factors that may affect GP’s attitudes to diagnosing COPD.

2.17 Diagnosis of COPD by GPs

The confidence of GPs in diagnosing COPD was surveyed in the UK in 2001 and 2005, during which time the ratings of ‘confident’ or ‘very confident’ increased from 52% to 80%. Spirometry was stated as the most important investigation. GPs’ having a high level of confidence in using spirometry had increased over the same period

from 42% to 72% (125). However, actual practice may differ as only 36% of GPs using case scenarios suggested spirometry although they cited COPD as a diagnosis and the proportion of GPs' who had actually used spirometry at the time of diagnosis was far lower (100).

In another study using standardised scenarios to examine the impact of spirometry on the decision making process, an average of 2.05 diagnoses were considered by GPs before spirometry and 1.35 diagnoses afterwards. This equated to a reduced odds ratio (OR) for considering more than one diagnosis, OR 0.27 (95%CI 0.20 to 0.35). There was also a significant increase in the OR for using a diagnostic prednisolone course, 4.56 (95% CI 3.12 to 6.64) and referral to a specialist, 7.26 (95% CI 4.71 to 11.20) (124).

When a sample of patients who had spirometry testing by a community service in one primary care area in the UK was followed up, 58% had either a new or changed diagnosis (COPD in 72%). However, interpretation of spirometry was provided to GPs with the spirometric indices (126).

2.18 Advantages for primary care-based case finding of COPD

Obstructive lung disease may be present without patients acknowledging it or reporting symptoms (74,127). Half the adults participating in a general population survey in the UK were unaware that respiratory symptoms could be a sign of a serious lung disease (128). Impaired quality of life due to breathlessness and fatigue was found to be a significant predictor of consultation among patients in the Netherlands. Objectively reduced lung function itself was not associated with consultation (74).

Practical means of improving the diagnosis of COPD are likely to be most effective if based in general practice, where a large proportion of a total practice population will consult their GP in any one year (129). The likelihood of seeing a GP increases with age. In a population survey in the UK in 2004, 12% of adults aged 16 to 44 had consulted a GP in the previous 14 days compared with 20% if aged 75 and over (130). The relationship with GPs and other providers in primary care is also highly valued by most patients, particularly if a problem is long term or complex, as is the case with COPD (131).

2.19 Models of spirometry provision to primary care patients

There are little data on the most effective delivery model to detect airflow limitation with spirometry. In the UK, a hospital-based lung function laboratory was the preferred venue for 33% of patients in whom there was a clinical suspicion of COPD, chosen in preference to one of four sessions offered in the community (132). Also in the UK, practice-based opportunistic spirometry screening assessments were successful for 94% of patients but a home visit for spirometry was successful for only 33% of patients (110).

2.20 Smoking and COPD

Internationally, tobacco use is recognised as the single most important preventable risk to human health and remains the single most important cause of COPD (10,133). Numerous pulmonary function abnormalities have been documented in smokers. In general, current smokers have a lower FEV 1 (134) and an accelerated decline in FEV 1 (16,17,135) compared to those who formerly or never smoked. Both of these associations show a dose-response relationship (134,136), while data from both prospective and retrospective studies have consistently reported increased mortality from COPD (4,137,138).

Smoking cessation has been shown to stop the accelerated decline in lung function that occurs in COPD (16,139) and the strongest rationale for early detection of COPD is the possibility that a patient's knowledge of their disease (i.e. having reduced FEV1) might enhance their smoking cessation efforts(93). All guidelines on the management of COPD include recommendations on smoking cessation (3,10-12,15) and strategies to assist patients have been promoted in a number of evidence based guidelines (140,141) and Cochrane systematic reviews (142-147).

2.21 Smoking prevalence in Australia

Smoking prevalence in Australia has been decreasing in recent decades. A fall was found between 1985 and 1995, from 34% to 27% for men and 29% to 23% for women (148). In 2004, 17.4% of the population aged 14 years and over reported smoking daily, a decline from 19.5% in 2001 (149). Tasmania had the third highest smoking prevalence in Australia when measured in the Australian Bureau of Statistics National Health Survey in 2001 (150). It estimated that 24.4% of the

Tasmanian population aged 18 years and over were current smokers. The picture for the future did not look optimistic either, with an increase in numbers of young people in the 16-17 year old group smoking regularly found in the Tasmanian component of the Australian Secondary Schools Alcohol and Drug Survey conducted in 2002 (151). The survey concluded that 17% of Tasmanians aged between 12 and 17 years are current smokers.

2.22 Health-related behaviour change applied to smoking cessation

2.22.1 Health behaviour definitions and models

Health behaviours are activities carried out by people to prevent disease, to detect it at an asymptomatic stage, to delay disease progression or to improve general well being (152). Such behaviours include not smoking, moderating alcohol intake, taking regular exercise and maintaining a normal weight. The relationship between beliefs concerning health maintenance and health behaviour have been represented in a number of models that have attempted to link attitudes, beliefs and emotions to behaviour (153-155). Some factors that are important, and shared by many models, are intentions to perform a behaviour, environmental constraints to the behaviour, skills, expectations regarding the outcome of the behaviour, social norms, self standards, affect and self-confidence with respect to the behaviour (156).

In the Social Cognitive Theory of Bandura (155), the postulated links between a person's cognitions and their behaviours are mediated through two processes. Firstly, self-efficacy or the self-perception of having the skills to perform a behaviour. Secondly, the expectation that a positive outcome, physical or social, will occur as a function of the behaviour.

When examining efforts in primary care to influence patients' health behaviour in various areas, traditional strategies have relied mainly on 'expert' or 'information' power (156). However, approaches or interventions based on health-behaviour models have been increasingly used, especially in the area of smoking cessation. In the Social Cognitive Theory(155), actions that are theoretically useful include increasing outcome expectancy for smoking cessation (for example by knowing that lung damage will decrease) and increasing self-efficacy (156).

2.22.2 Changing health behaviour

In relation to changing health behaviour, it is recognized that individuals vary in their readiness to embark on a change (157). Achieving a change in health-related behaviour can be viewed in psychology as either a continuum or as a series of stages (158). Using the concept of stages of contemplating change, deciding to change, making a short-term change and continuing long-term change, a number of models have been proposed (158).

One such stage model initially applied to smoking cessation is known as the Transtheoretical Model. In the model there are three dimensions that represent critical elements in the change process: stages, processes and levels of change (159). The stages of change represent the temporal and motivational aspects of behaviour change. The processes of change are mechanisms that facilitate movement through the stages. The third dimension of the model involves possible problems in various areas of an individual's life (such as personal or social difficulties) that complicate and interfere with change.

2.23 Transtheoretical Model of smoking cessation

2.23.1 Theoretical basis and utility of the model

The Transtheoretical Model is based on findings in the 1980s that there were differences in the use of specific processes of change by smokers in relation to smoking cessation during periods of decision making, active change and when maintaining change. (160,161). Five experiential processes were predominant when contemplating change: consciousness raising, dramatic relief, environmental re-evaluation, social liberation and self re-evaluation. The use of five behavioural or verbal processes: helping relationships, stimulus control, counter-conditioning, reinforcement management and self-liberation, clustered during active change, although there was a correlation between types of process (162). Individuals not contemplating any behaviour change used fewest processes (163).

The model has also been used to describe change in a variety of other behaviours such as obesity, exercise, mammography screening and illicit drug use (164).

There is good evidence for construct validity of the model in smoking cessation and its predictive validity. Cross sectional studies have confirmed that smokers in the stages of precontemplation, contemplation and preparation differ in the psychological determinants of readiness to change, mainly expectation of outcome

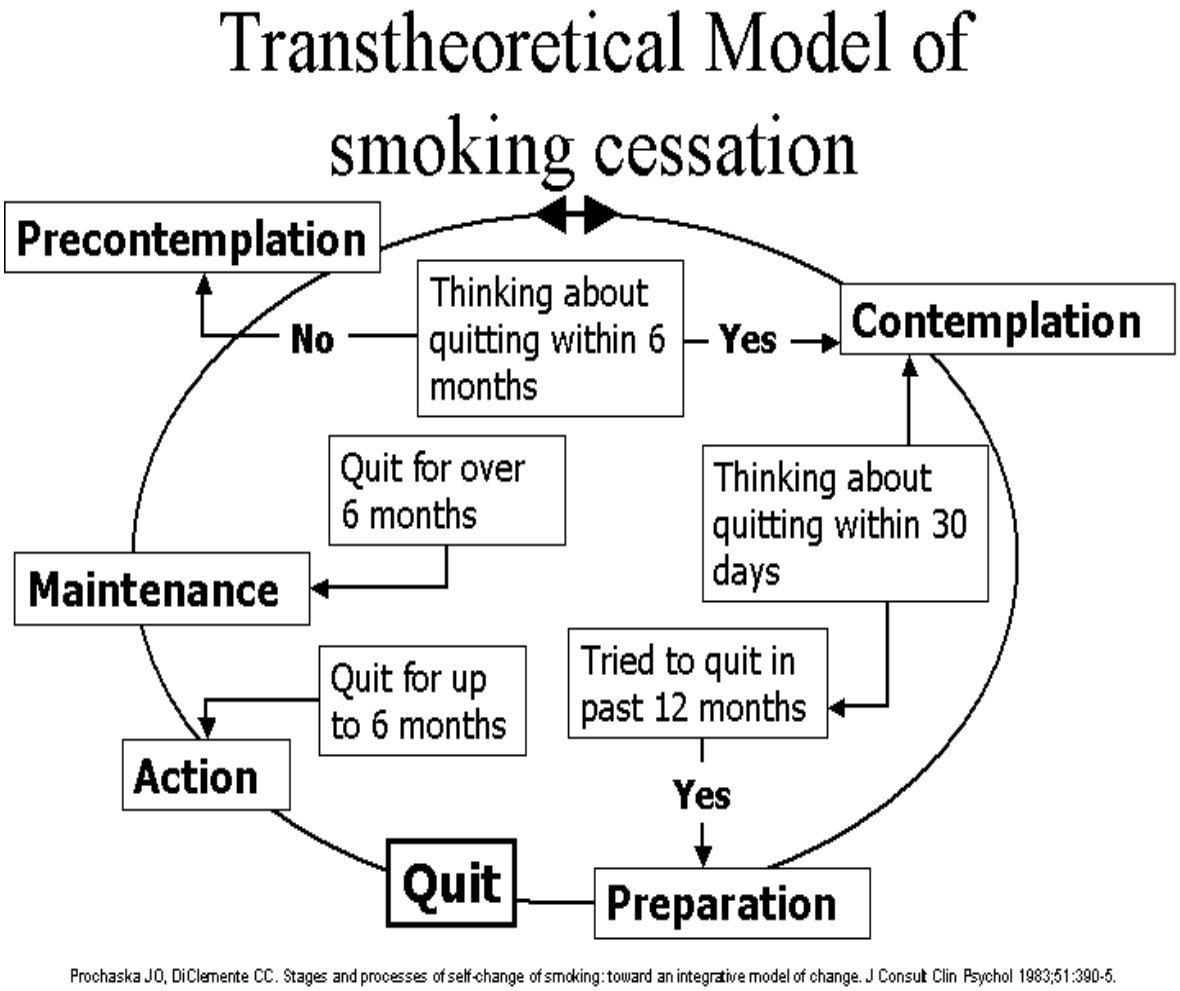
and perceived self-efficacy rather than measures of smoking behaviour (165,166). A mathematical approach has been used to validate the temporal organization of smoking cessation into stages (167,168). Markov chain analysis of shifts between stages, confirm that the event was predicted by the event immediately preceding it. Very importantly, an individual smoker's position in the stages-of-change model is predictive of smoking cessation success measured later in time for both self-quitters (160) and those receiving smoking cessation interventions (166,167).

2.23.1 Description of model

The number of stages in the model and its division into time periods has varied since the initial, early description. However, as described more recently, five stages are identified and defined in a temporal order (Figure 2.2)(167).

1. Precontemplation: a period in which smokers are not thinking about quitting smoking (at least not in the next six months).
2. Contemplation: a period of time in which smokers are seriously thinking about quitting in the next six months
3. Preparation: a period when smokers who have tried to quit smoking in the past year seriously think about quitting in the next month.
4. Action: a period ranging up to six months after smokers have made an overt change and stopped smoking.
5. Maintenance: a period beginning six months after cessation and continuing until smoking is terminated as a problem.

Figure 2.2: A diagrammatic representation of the five stages in the Transtheoretical Model of smoking cessation.



2.23.3 Using the model to design interventions for smoking cessation

The Transtheoretical Model has been used extensively to guide smoking cessation interventions that are tailored to a specific stage of change (167,169-172). There is some controversy over this elevation of a structural model to the theory level (173) and a systematic review of the effectiveness of stage-based interventions to promote smoking cessation concluded that stage-based interventions are no more effective than non-stage based interventions or no intervention in changing smoking behaviour (174).

2.23.4 Factors affecting the stage of readiness to quit

A smoker's stage of readiness to quit is affected by many factors: social, behavioural and psychological. In a study of smokers (n=506) attending a health maintenance organisation in the USA (175), the likelihood of being in a higher level of readiness to quit was greater for those who smoked fewer cigarettes per day and those who attributed symptoms to smoking. Age was not significantly associated with stages of change. Smokers who perceived very important health benefits compared to fewer benefits from quitting smoking and those who perceived that others wanted them to quit smoking very much were also more likely to be in a higher stage of readiness.
In a study in primary care in the UK, smokers were surveyed on their respiratory symptoms, smoking behaviour, quit attempts, self-efficacy and recall of smoking cessation advice. Those with one or more symptoms, who attributed them to smoking, were eight times more likely to believe that their health would improve if they stopped smoking and six times more likely to intend to stop smoking (176).
In a study in the Netherlands in 633 patients with COPD, those in the stages of contemplation/preparation had significantly greater expectations of improved health from quitting and greater social support for quitting from significant people in their lives than those in precontemplation (177).

2.23.5 Self-efficacy and smoking cessation

According to the Social Cognitive Theory of Bandura (155,178), significant differences are expected between self-efficacy levels for individuals in subsequent stages from contemplation to maintenance. There is evidence confirming this in a number of different settings, with later stages having the highest self-efficacy expectations toward non-smoking among smokers in the general community (179) and smokers with COPD (177). Self-efficacy can be increased by the use of

interventions. In smokers with low readiness to change, an increase in self-efficacy scores occurred when quit information was given. The effects were significantly greater after receiving multiple letters, individually tailored to the stage of change, compared to a single tailored letter or a self-help guide (169). The level of self-efficacy of an individual also predicts actual quitting in unselected smokers (180,181) and smokers with COPD (182).

2.24 Outcomes in studies of smoking cessation

2.24.1 Prevalence rates

Traditionally, smoking cessation studies have used smoker and non-smoker categories to represent individual trying to quit smoking (183). This is either based on self-report or use of a validation measurement, such as exhaled carbon monoxide or urinary nicotine metabolites (184). Point prevalence measures reflect the percentage of patients not smoking at different points in time after a specified period of abstinence (24 hours, 7 days, 30 days etc) (183). However, in terms of the Transtheoretical Model of smoking cessation, these measures are only relevant to the transition from preparation to action and do not capture earlier change in willingness or readiness to stop smoking.

2.24.2 Smoking cessation studies using movement in stage of change as an outcome

There is evidence that smokers in the later stages of readiness to change have higher cessation rates (160,166,167) and if a smoker progresses from one stage to the next, the chance of taking action in the next six months is increased (164). Thus, movement forward in the model may be a valuable outcome measurement in itself in studies exploring the effect of interventions in smoking cessation, especially in an exploratory study (185) or as a surrogate measure for cessation.

A study in the USA, comparing the effect of a tailored multi-modal intervention with a self-help strategy on smoking cessation and intention to change smoking behaviour, found a significant increase in positive progress along the stages of change for the intervention group compared to self-help group (OR 1.68, p=0.04) despite no difference in validated quit rates (OR 1.4, p=0.35) after one year (186). Tailored self-help interventions also led to significantly more positive stage transition in those not considering quitting at all compared to no information (169).

In a study of smokers receiving counselling from physicians trained in using behavioural theory compared to physicians without training, at one year there was both a significant increase in smoking cessation (OR 2.8, 95% CI 1.4 to 5.5) and in willingness to quit (p=0.007) (170).

2.25 The effect of spirometry on smoking cessation

Studies of the influence of spirometric testing on actual quit rates have not been conclusive(53). It is likely that there will be much greater power in a study of an intervention to detect forward shift in preparedness to quit compared to actual quit rates, and yet at a population level such an intervention would have a major effect on quitting. Because of the number of individuals required in a study whose outcome was sustained cessation, the likelihood of a Type II statistical error is increased.

2.25.1 Systematic review of intervention studies

An evidence-based systematic review published in 2005 evaluated seven studies in which the intervention included the process of obtaining and providing the results of spirometry to smokers, combined with smoking cessation counselling (53). However, in six of the studies more than one intervention was evaluated in the experimental group as compared to the control group. No pooled estimate of smoking cessation rates could be performed owing to the heterogeneity of interventions and the report recommended that randomised control trials should be undertaken to assess the effect of spirometry in primary care on smoking cessation.

2.25.2 Observational studies of spirometry and smoking cessation

In a community-based study of men aged 30-45 years in Norway who had spirometry, a random sample received advice on smoking cessation with their spirometry results and a control group received no advice or results. Self-reported smoking cessation was measured at twelve months, with the difference found between the intervention group and the control group for overall cessation rates using an intention to treat analysis just failing to achieve statistical significance (11.4% versus 9.1%, p=0.05) (187).

A community spirometry screening survey aimed at smokers aged over 30 years was conducted in ten separate communities in the USA in 1973. Results were classified into abnormal (FEV1/FVC < 0.7 or $FEF_{25-75\%}$ < 55% predicted) or normal

(FEV1/FVC ≥ 0.7, FVC ≥ 70% predicted) and a letter notified only those participants with abnormal lung function. The letter instructed them to see their physician, who organized follow up and gave advice on smoking cessation. In three randomly selected communities, those who were smokers at the time of screening were followed up by questionnaire for up to three years. Among subjects with abnormal lung function and no previous knowledge of having respiratory disease (n=1296), the sustained quit rate was 21.4% while it was 11.7% among those with normal lung function (n=298) (188). Although this was reported as a significant difference ($p< 0.01$) there are a number of limitations in this study. There was incorrect feedback to some subjects on the status of their lung function, a quarter of those notified about abnormal lung function did not consult a physician as instructed and subjects with normal lung function in the control group were not given any advice to quit.

2.25.3 Randomised studies of spirometry and smoking cessation

To date most studies using spirometry to increase smoking cessation have limitations that may affect the strength or validity of their results. In a study in Italy, general practitioners randomised patients to a control group that received brief quit advice with printed smoking cessation materials or to one of three interventions: repeated counselling, repeated counselling with nicotine replacement therapy or repeated counselling with spirometry (189). There were no significant differences in validated smoking cessation rates after twelve months among participants in any intervention group compared to the control group. In the group allocated to the spirometry intervention, 6.5% achieved sustained smoking cessation compared to 4.8% in those who only received counselling. Results in this study are limited by less than full application of the intervention, with only 50% of the selected spirometry group actually attending for testing.

A small study of US Veterans in 1990 attending a health promotion clinic (n=99), compared those who had spirometry, motivational counselling and an educational smoking cessation intervention with those receiving the educational intervention alone (190). At twelve months, self-reported smoking cessation rate was 24.4% in the spirometry group and 11.1% in the education only group ($p=0.08$). Biochemically validated cessation was found in 20.0% and 6.7% of the groups respectively ($p=0.06$).

A study of patients attending family practice clinics was carried in 1996 in the USA. Smokers (n=205) were randomly allocated to have standard smoking cessation

advice suited to their motivational stage or the same standard advice plus spirometry, feedback on the result and exhaled breath carbon monoxide testing (122). There was no statistically significant difference in the sustained self reported quit rates after nine months between groups, with 9% in the spirometry group and 14% in the education only group quitting.

2.26 Knowledge of abnormal lung function and smoking cessation

One concern that has been raised concerning the strategy of using spirometry and providing feedback on the results to smokers is the potential for decreased smoking cessation rates due to false reassurance or nihilism in those with normal spirometry (53).

Smoking cessation rates appear to be higher in those with obstructive lung function compared to normal lung function in observational studies. In a community-based study in Poland in 1999, lung function was measured in smokers aged over 40 years with a smoking history of at least ten pack-years (191). All smokers received similar verbal advice to stop smoking, and printed materials containing information on the harmful effects of smoking and advice on quitting. The spirometry criterion used to classify obstructive lung function was based on a ratio of FEV1/FVC less than 85% of the predicted normal value. In a sample of 558 smokers recruited in a single chest clinic in the capital city, after twelve months there was no statistically significant difference in sustained, validated quit rates between the group with obstructive lung function (n=297) or the group with normal lung function (n=261); 10.1% versus 8.4% (192). When the same study was reported later, included at that time the results for a larger sample of 3,441 smokers recruited from ten of the participating chest clinics, the difference had become statistically significant (193). The validated quit rate for those with obstructive lung function was 16.3% compared to 12.0% for those with normal spirometry (p=0.0003). Recruitment in the study was by advertisement so those involved needed sufficient motivation to volunteer (191).

A recent study in primary care in Sweden, recruited 512 smokers who had spirometry performed. The ERS definition (12) was used to define smokers with COPD. Two groups were followed up with annual spirometry and received brief smoking cessation advice, one group with normal lung function (n=161) and a group with COPD (n=119). A third group with normal lung function was selected by uneven birth date for follow up spirometry at three years only (n=165). All

participants received a personal letter from their physician with the results of their spirometry test and a letter on the advantages of smoking cessation (194). The self-reported 30-day smoking cessation rates after one year were 18% for the COPD group compared to 5% for those with normal lung function. After three years, point prevalence abstinence rates were 29% in the COPD group and 14% in the normal lung function group with annual follow up (p=0.003) and 15% in the group with normal lung function with no intervening spirometry. However, pharmacological smoking cessation therapies were used by significantly more smokers who achieved cessation in the COPD group compared to the normal lung function group.
What is lacking in all these studies are data on the potential negative effects of a normal spirometry result.

2.27 Qualitative-quantitative research approaches in COPD

This thesis contains results from research that uses both quantitative and qualitative designs and this section of the literature review contains a definition of qualitative research and a description of qualitative research methodology. The differences between qualitative and quantitative research methods are highlighted and the advantages of combining both in a mixed-methods study are explained.

2.27.1 Basis of qualitative research methods

Qualitative research aims to investigate behaviours, understandings, actions and experiences in a natural setting (195). It is generally composed of three essential elements: the collection of data, selection of a theoretical framework that underpins the research, and placing the collected data within the specified framework for analysis and interpretation (196). There is considerable theoretical plurality in the design of qualitative research, which may be both concept or theory driven and theory generating. However, not all qualitative studies have an explicit focus on theory, sometimes the design of a study is method-driven with the choice of method based on pragmatic reasons (197). This is especially true in applied health services research in which the research question arises from a specific practical problem (198), such as in this investigation into the use of a clinical test (spirometry) in primary care and how this can be promoted in a clinical setting.
The setting in which research is conducted usually differs between quantitative and qualitative research, with qualitative research being conducted in a natural compared

to an experimental or controlled setting. This follows from the different aims of the two methods, with hypothesis-testing dominating in quantitative research and hypothesis-generation being central to qualitative research (197).

Qualitative research is differentiated by its use of inductive logic compared to the deductive logic characteristic of quantitative research (199). This is typified in the generation of theory that is grounded in the data collected, as compared to a priori theory testing. Glaser and Strauss described this as a process by which the theory is "discovered, developed and provisionally verified through data collection and analysis" (200).

Underlying the majority of qualitative research is the identification of concepts, themes and categories, and their linkage into a theoretical framework (201). This process is typified in an approach termed "thematic analysis" (202). The practice of thematic analysis varies however, with differences existing between researchers over the use of pre-existing categories, a practice avoided in grounded theory (200,203). However, both use the same underlying processes of coding, sorting and organising data. The same processes are used in iterative thematic analysis, when the areas of interest are suggested by the research problem and questions. Iterative thematic analysis uses a process of constant analysis and reflection during the collection of new data, and aims to identify reasons or explanations for behaviour. Narrative analysis in contrast, takes account of the structure of the narrative as a whole (201) and has considerable value when seeking to understand peoples' own experience of illness and medical procedures (204).

Thus, in contrast to quantitative methods, qualitative research aims to understand behaviour and why it varies (198). It allows in-depth exploration of an issue and individual viewpoints, attributes that give it high validity. Quantitative research on the other hand, measures behaviour using standardised tools so that assessment can be considered consistent and reliable across a group or population.

2.27.2 Methods used in qualitative research

Qualitative research uses field-based methods that collect first order data from participant observation, or second-order data from participant interviews (196). Interviews elicit the beliefs and views of individuals from their perspective and can be conducted in a structured, semi-structured or entirely unstructured manner, the latter used to avoid a controlling style of discussion (205). However, in order to collect and compare data that is a reflection of participants' views on health-related

issues, semi-structured interviews are frequently preferred. These use an interview guide with open-ended questions going from general to specific topics in a funnelling manner (196). A focus group is a specific type of group interview; often conducted in a semi-structured manner that enables exploration of a particular set of issues (206). The specific differentiation of a focus group from an interview lies in the role of interaction between participants (207). This element may add to the understanding achieved through interviews by identifying group norms, differences between individuals, reflection by participants on others' ideas, and arguments against others' ideas (208).

2.27.3 Combining qualitative and quantitative research

In the assessment of a health care intervention, traditional quantitative methods can provide an estimate of the presence and size of an effect. However, in the complex area of operational health services research where an intervention is affected by the differing views of health professionals, patient behaviour and experience, and varying practice structures, quantitative results alone may give incomplete or inconsistent results on effectiveness (199,209).

Traditional intervention studies belong to the quantitative or positivist paradigm of investigation based on concepts of 'cause', 'effect' and 'objectivity' (196). Qualitative research however, through an interpretive and naturalistic approach, may collect more situational information that leads to the discovery of alternative hypotheses (195). While the relevance and applicability of findings in qualitative studies may be limited by lack of generalisability, its supplementary role to quantitative research allows 'triangulation', i.e. validation or confirmation of findings (197).

Alternatively, a qualitative research design may be combined with quantitative data collection in a multi-method approach of complementary nature, to provide different levels of data that are used to build a wider picture (198). This approach has value above that of purely cross-validating and confirming results (209). Integrated multi-method research may use quantitative and qualitative techniques sequentially or concurrently (210). Either type of research method may be designated as the principal or complementary method , and depending on the nature of the topic, the complementary method may be used as a preliminary or follow up to the principal method (211).

2.27.4 Qualitative studies in chronic respiratory disease

Qualitative research has been used to investigate a number of facets of COPD, including an examination of how people cope in daily life with recognised established disease (212-214), the factors that influence hospitalisation for exacerbations (215) and communication of prognosis in COPD (216). Results from interviews with those affected by moderate or severe COPD have shown that the disease causes anxiety, emotional frustration and social loss for patients (212,214,217). This mirrors the reduction in quality of life found with quantitative studies in similar disease severity using disease specific standardised measurement instruments (218). Quantitative research methods have been used to investigate what aspects of the disease mediate the impairment of quality of life seen in COPD (219) and qualitative methods have been used to achieve the same aim (212,217), and also to assist patients develop strategies that improve their quality of life.

Qualitative research suggests that the cause of COPD is poorly understood by some patients (212), although their understanding of the cause of exacerbations in established disease may be better (215). There is however, a lack studies in the current literature looking specifically at patients' experiences and acceptance of the process of diagnosis in COPD and how this may be affected by their beliefs about the cause and nature of COPD.

Frequently, findings from qualitative research into health-related areas are based on data collected only from patients but these methods can also be used to explore the views of doctors. Qualitative studies have been used with doctors to examine their views on education of patients with COPD (220) and the use of spirometry in asthma care (221) but few have investigated their attitudes to the diagnosis or management of COPD.

A study on doctors in primary care, conducted around fifteen years ago in Canada, before national or international guidelines on COPD were issued, used structured interviews and clinical case scenarios to investigate the diagnosis of COPD. An enumerative analysis of the data found that doctors had a low threshold of suspicion of COPD and rarely performed lung function tests for diagnosis. However, no thematic content analysis was performed to investigate their attitudes or the reasons that might explain the low use of spirometry (222).

A mixed-methods study of primary care in the USA using observation of patient encounters and medical records data (223) found that doctors acknowledged the need to provide clinical services in three areas: acute care, managing chronic problems and

prevention. However preventive care delivery was the most variable and was influenced by competing demands and priorities and particularly by the presence of individual doctors with enthusiasm for prevention. These preventive services form the interface to recognition of chronic disease at an early stage and an exploration of doctors' views may lead to understanding why preventive practices are low and how to improve them. In COPD this may lead to earlier recognition of disease and intervention to prevent deterioration.

An extension of the mixed-methods approach may be used with parallel examination of views of both patients and doctors about a clinical topic or intervention. This may result in an intervention operating more successfully if developed from the viewpoint of both patients and physicians rather than from the "top-down," i.e. without an understanding of the behaviour, views and beliefs of recipients and users (224). Better understanding of both doctors' and patients' attitudes to the diagnosis of COPD may lead to increased prevention through designing an optimal spirometry intervention for identification of early disease.

2.27.5 Choice of research method for studies reported in this thesis

There is currently a lack of information on what barriers exist for both patients and doctors to earlier diagnosis of COPD and this issue is well suited to exploration by mixed-methods qualitative/quantitative research. This thesis contains results from a preliminary study that used a sequence of principal qualitative data collection from patients with COPD and their general practitioners and complementary quantitative data collection from patients and practice records, to generate hypotheses.

A subsequent intervention study of models for providing spirometry in primary care used qualitative data collection from doctors on their perspectives and experiences to complement, evaluate and assist in explaining the principal quantitative findings in the comparison of models.

Chapter 3

Preliminary study

3.1 Introduction

A preliminary study in primary care in the local region was planned to investigate how patients acquired the diagnostic label of Chronic Obstructive Pulmonary Disease (COPD) or emphysema, and to identify the factors that influenced diagnosis and management and attitudes of doctors and patients to COPD. At the time the investigation commenced in October 2002, international guidelines for the diagnosis, management and prevention of COPD had already been published (10) and Australian guidelines were in preparation (3).

The aims were to investigate:

1. How GPs diagnose COPD
2. The use of spirometry in diagnosing COPD
3. GPs' understandings and beliefs about COPD
4. The severity of COPD in general practice
5. The impact on patients of recognised COPD
6. Patients' understandings of COPD and its causation.

3.2 Ethics approval and consent

Approval for the conduct of the study was obtained from the Human Research Ethics Committee of the University of Tasmania prior to commencing the study. Doctors at participating practices were given information about the study and asked to select patients meeting the inclusion criteria. These patients were sent information on the study and an invitation to contact the study investigator if they were willing to participate. Those patients who agreed to participate gave informed consent prior to the commencement of any interview or assessments (Appendix 1a). Doctors gave consent to the examination of their practice records and to their participation in a focus group or interview on the topic of COPD [Appendix 1b].

3.3 Methods

3.3.1 Practice selection

In 2002, two practices in the Hobart area, selected because of their location in different geographical areas, were recruited through personal contact with academic research teams.

3.3.2 Patient selection

A recruitment target of fifty patients with a diagnosis of COPD was set. It was planned to conduct semi-structured interviews with a sub-sample of up to twenty patients. Potential participants included all patients diagnosed with COPD or emphysema in the practices. Practice databases in Medical Director were searched by diagnosis and prescribed medications; inhaled short-acting beta-2 agonists, inhaled anticholinergics, and oral theophylline. From search results, GPs were asked to review the list to check the diagnosis of COPD for their patients and to exclude any with cognitive impairment and those too unwell with another medical condition. Investigators had no role in the selection of patients who were considered by GPs to meet inclusion criteria. The patients selected were sent a letter describing the study and asked to contact the research team office for more information. Patients willing to participate gave informed consent and were offered an appointment for an interview with a researcher trained in conducting semi-structured interviews. An appointment for a clinical assessment was arranged to follow the interview for those who participated in a semi-structured interview. Interviews and clinical assessments were carried out at either the patient's practice or at their home according to their preference.

3.3.3 Data collection

3.3.3.1 Spirometry

A trained respiratory nurse performed spirometry using a portable Microlab 3300 spirometer. Three forced expiratory manoeuvres which met the ATS standards for acceptability (225) were obtained where possible and repeated 15 minutes after the administration of salbutamol, 400mcg via a spacer. Results were classified into four groups based on post-bronchodilator values (unless the patient had only performed pre-bronchodilator testing):

1. COPD: FEV1/FVC ratio <0.7. Severity was based on the GOLD classification (10) using FEV % predicted: mild ≥80%, moderate 50-79%, severe 30-49%, and very severe <30%
2. Asthma: post-bronchodilator increase in FEV1 > 200ml and ≥12% and post-bronchodilator FEV1/FVC ≥0.7.
3. Small airways disease (SAD): mid-expiratory flow ($MEF_{25-75\%}$) <55% predicted and flow-volume curve configuration convex to volume axis on downward limb (in the presence of normal FEV1, FVC and FEV1/FVC ratio).
4. Restrictive or mixed obstructive-restrictive pattern: FVC <80% predicted, FEV1/FVC ratio ≥0.7.

3.3.3.2 Measurement of quality of life

The St. George's Respiratory Questionnaire (SGRQ) (226) was used to measure health related quality of life. It was devised to provide a measure of quality of life specifically in airways disease and be more sensitive than general quality of life measures. The SGRQ has been shown to be sensitive and repeatable. A difference in total score of about four points indicates a clinically significant difference between populations (226). An improvement of about four points also indicates a clinically important therapeutic effect (227). The SGRQ is applicable in a range of disease severity (228). There are seventy-six items, relating to frequency and severity of respiratory symptoms, activities that cause or are limited by breathlessness, impacts on social functioning or psychological disturbance resulting from respiratory disease. Participants completed the questionnaire during the clinical assessment and without assistance. It was checked for completeness by the researcher. The total score and subscale scores for symptoms, activity and impacts were calculated.

3.3.3.3 Screening for psychological symptoms

Questionnaires are effective in increasing recognition of anxiety and depression in a general practice population (229). A screening questionnaire designed for use during a short interview was used to screen for anxiety and depression (230). It was derived in specialist psychiatric practice from four screening questions for latent traits of anxiety or depression, and five additional probe questions for each trait. A cut off threshold for the screening questions was identified and symptom questions were phrased in non-technical language. The anxiety and depression scales were shown to

have sensitivities of 82% and 85% respectively and positive predictive values of 0.56 and 0.85 respectively.

A screening test for anxiety and depression

Screening questions for anxiety:

1. Have you felt keyed up, on edge?
2. Have you been worried a lot?
3. Have you been irritable?
4. Have you had difficulty relaxing?

If positive answers are given to at least two of the above questions, probe questions (5-9) are asked.

5. Have you been sleeping poorly?
6. Have you had headaches or neck aches?
7. Have you had any of the following:
   trembling, tingling, dizzy spells, sweating, frequency or diarrhoea?
8. Have you been worried about your health?
9. Have you had difficulty falling asleep?

Each positive answer scores 1 and a total positive score of 5 indicates a 50% chance of having a clinically important disturbance of mood. The probability rises sharply for scores above 5.

Screening questions for depression:

1. Have you had low energy?
2. Have you had loss of interests?
3. Have you lost confidence in yourself?
4. Have you felt hopeless?

If positive answers are given to at least two of the above questions, probe questions (5-9) are asked.

5. Have you had difficulty concentrating?
6. Have you lost weight (due to loss of appetite)?
7. Have you been waking early?
8. Have you felt slowed up?
9. Have you tended to feel worse in the morning?

A total positive score of 2 means a 50% probability of a clinically important mood disturbance. The probability rises sharply for scores above 2.

3.3.3.4 Assessment of respiratory health and exposures

Respiratory health was assessed using the European Community Respiratory Health Survey (ECHRS) laboratory questionnaire developed for use in stage II of the survey with participants selected for clinical and functional assessment (62). This includes questions on respiratory symptoms and diagnoses, family history, employment, environmental exposures, smoking, medication use and use of health services for respiratory complaints.

3.3.3.5 Assessment of atopy

Skin prick allergen testing was undertaken, consisting of the intra-epidermal injection of minute amounts of standardised glycerinated antigen solutions, a negative control (diluent) and a positive control (histamine acid phosphate). A wheal $\geq$3mm diameter was considered a positive result, provided that the negative control was non-reactive (231). A positive reaction indicates the presence of specific IgE antibody to the antigen administered. Positive reactions to multiple antigens indicate an atopic state. Positive reactions to the negative control and all antigens suggest dermatographia (232).

Six common aero-allergens were used; cat hair, D. pteronyssinus, mould mix, aspergillus fumigatus, perennial rye and grass mix with histamine as a positive control and glycerin/saline as a negative control (Manufacturer Hollister-Stier, USA, supplier Ebos Group, Sydney).

3.3.3.6 Patient record review

Data was extracted from practice records (paper and computer) according to a template designed for the study. Specific recording of the following items was sought for two periods, around the time of diagnosis and during recent management (defined as the previous two years):

1. Respiratory symptoms
2. Respiratory diagnoses and dates of diagnosis
3. Other diagnoses
4. Smoking status, advice or interventions relating to smoking cessation
5. Investigations for respiratory disease: spirometry (including who ordered or performed the test), chest radiology, steroid trial
6. Prescription of inhaled corticosteroids
7. Referral for specialist opinion

8. Psychosocial history: employment status, anxiety, depression
9. Functional dyspnoea with specific activities
10. Exacerbations of COPD, episodes of bronchitis and hospital admissions
11. Medication for COPD, dates commenced and indications.

3.3.3.7. Qualitative data collection

Qualitative research was used in this preliminary study to explore patients' understanding and beliefs about COPD and their GPs' attitudes and beliefs about COPD. Interview and focus group data were analysed to generate hypotheses about spirometry use and earlier diagnosis of COPD (198).

3.3.3.7.1 Semi-structured interviews with patients

Interviews with participants with COPD were chosen for in-depth exploration of their experiences. They were conducted through face-to-face conversation in a non-medical setting that was comfortable and familiar to the participant (207). The participants were selected from the patient list in each practice to achieve a purposive sample with balance in gender, age and disease severity. Participants were interviewed before measurement of their lung function or completion of questionnaires, in order not to influence their responses. Interviews were analysed shortly after recording and while further interviews were being conducted to allow emerging areas of interest or insights gained in previous interviews to inform ongoing interviews (205). Interviews were conducted until no new themes emerged during analysis, indicating that data saturation had been achieved (233). Interviews were taped and transcribed verbatim.

The aim was to explore the topic of COPD in detail by giving the individual participant the opportunity to describe their explanatory model (234). This is a term used in medical anthropology referring to the understandings that any individual has about a particular illness including opinions about cause, management, and prognosis (235). The explanatory model for each participant was built up from their description of the illness using the following prompts to allow them to express their experiences and beliefs about their lung disease:

1. What do you call the problem?
2. What do you think caused the problem?
3. Why do you think it started when it did?
4. What do you think the sickness does? How does it work?

5. How severe is the sickness?
6. Will it have a long course?
7. What kind of treatment do you think you should receive for the sickness?
8. What are the most important results you hope to receive from this treatment?
9. What are the chief problems the sickness has caused?
10. What aspect of the illness worries you most?

Participants were not asked direct questions about smoking or smoking cessation during interviews to avoid any appearance of being judgemental and making interviewees defensive, which might colour their responses.

3.3.3.7.2 Focus groups and semi-structured interview with doctors

Even in a single practice entity, there will be a range of beliefs and attitudes held by doctors (236). Focus group discussions enable both expression of individual beliefs and interaction with other individuals to explore differences and support or question others' beliefs in a controlled setting (237). Such discussions may therefore provide additional understandings compared to private individual interviews alone (208).
A focus group discussion was held with doctors in each practice. A trained researcher acted as facilitator, with a note-taker present to record the order of speakers, the initial words spoken by each and non-verbal interaction (205). Individual interviews were conducted on a one-to-one basis with a small number of doctors. These were available for doctors who were willing and able to devote the time or who were unable to attend the focus group. Focus group discussions and interviews were recorded and transcribed verbatim. They were analysed in parallel, with the interviews being used to seek additional information that had not emerged in the focus groups. The facilitator and interviewer used the following prompts to guide discussion in both cases:

1. Give a definition of COPD.
2. Describe a typical COPD patient in the practice.
3. How do you diagnose COPD?
4. When do you record a formal diagnosis?
5. Do you attempt to differentiate between asthma/emphysema/chronic bronchitis?
6. Use of spirometer.
7. Use of radiology.
8. Use of steroid trials.

9. Role of respiratory specialist.
10. Psychological symptoms in COPD.
11. Awareness of COPDX guidelines.

3.3.3.8 Analysis framework for interviews and focus groups

A rich body of data were collected from interviews with participants who had COPD and a number of different analyses were performed. These were divided on thematic lines as suggested by Sandelowski (238). Although all themes were discussed by at least two researchers, one researcher took the primary role in the analysis of each thematic area.

In this chapter, analysis focussed on the discovery and diagnostic process for COPD and prevention of COPD. These results are presented following the quantitative findings that describe the clinical practice of participating doctors as it relates to COPD and the severity of COPD and its impact on participating patients.

Data from doctors were analysed inductively with the aim of generating theories that could then be tested (198). They were complemented by results from practice records extraction to guide subsequent decisions on designing an intervention, as suggested in the priority sequence model of Morgan (211).

Analysis of all data was performed using an iterative framework in which a systematic examination of the transcription was conducted to identify codes, classify and develop categories and themes (206). The process was continued until all instances were compared and no new categories identified (198).

3.4 Results

3.4.1 Practices

Details of the two practices, in which a total of 19 GPs engaged in full-time or part-time practice, are shown in Table 3.1. Practice 1 was a suburban practice and Practice 2 covered an outer-urban and rural area. Data from the 2001 ABS census using the practice postcode indicated that the socio-economic status of the areas differed (239). In practice 2, there was a higher unemployment rate and lower median weekly rent. Household sizes were larger and there was a lower proportion of residents with qualifications post-school Year 12. However, median weekly family incomes were similar in both practices.

Practice 1 owned an electronic flow spirometer located in the treatment room. Practice 2 owned a bellows volume-displacement spirometer located in a little used practice room, described by doctors as “out the back”.

3.4.2 Participants

A search of practice prescribing databases yielded 106 potential participants. After review by GPs, information about the study was sent to 91 patients from the two practices. 45 patients (27 female) with a mean age of 67.8 years (SD 10.5) were willing to participate of whom 42 completed clinical assessments. Participation rates were 42.4% in Practice 1 and 53.5% in Practice 2. No data were available from Practice 1 on refusers, however in Practice 2 there was no significant difference between the mean age of those who declined to participate and those who agreed (71.1 versus 68.5, p=0.20) although reasons for non-participation were not given. Interviews were completed with 18 patients (12 female). We held two focus groups, involving 13 GPs (68%) and interviewed 3 in depth.

3.4.3 Withdrawals

One participant withdrew because of another serious illness before completing clinical assessment or interview. Two participants were interviewed and withdrew for personal reasons prior to clinical assessment. For the remaining 42 participants completing clinical assessments, there were no significant differences between practices for age, gender, smoking status, length of smoking history proportion of participants reporting respiratory diagnoses (Table 3.2). In view of this, data from both practices were combined for all other analyses.

Table 3.1: Demographics of practices in preliminary study and recruitment of participants.

Demographics of practices	*Practice 1*	*Practice 2*
Location	Suburban	Outer-urban/rural
Median weekly family income *	$600-$699	$600-$699
Mean household size*	2.3	2.8
Median weekly rent*	$100-$149	$50-$99
Unemployment rate*	11.99%	16.75%
% With educational qualification post Year 12*	26%	13%
Full time equivalent GPs in practice	7.5	5
Patients in practice	20,000	15,000
Patients identified by GP for study & sent information	33	58
Patients agreeing to participate	14	31

(*ABS data taken from the postcode of practice location.)

Table 3.2: Comparison of participants in two practices.

Patient characteristics	*Practice 1 n=14*	*Practice 2 n=28*
Age (years)	69.2 (7.8)	68.5 (10.7)
Male (%)	7 (50)	10 (36)
Ex-smoker (%)	11 (85)	21 (74)
Smoking exposure (pack years)	41.4 (12.6)	45.0 (12.7)
Documented diagnosis emphysema or COPD (%)	13 (93)	24 (85)
Documented diagnosis chronic bronchitis (%)	4 (31)	9 (32)
Cough in winter for >3mths, for 2 years (%)	6 (46)	14 (52)
Documented diagnosis asthma (%)	6 (46)	12 (43)
Patients reporting asthma diagnosis (%)	7 (58)	18 (67)
Patients atopic on skin prick testing (%)	4 (31)	10 (37)

Continuous data presented as mean (SD)

3.4.4 Diagnosis of respiratory disease

A diagnosis of COPD, emphysema or COAD was recorded for 36 (85%) participants who completed the clinical assessment. These terms were used with varying frequency in practice records. They were used interchangeably as diagnostic terms until guidelines introduced specific definitions for COPD from around 1995. The results included here use the term COPD, irrespective of which term was used in practice records. Additional diagnoses were also recorded in participants with COPD, asthma in 18 (50%) participants and chronic bronchitis in 13 (36%) participants.

3.4.5 Spirometry results

3.4.5.1 Patients with a diagnosis of COPD

Spirometry results were consistent with a diagnosis of COPD (FEV1/FVC <0.7) in 30 (83%) of the 36 participants with doctor-recorded COPD (Table 3.3). COPD classification of severity based on FEV1 % predicted using GOLD criteria (54), was moderate for 16 (53%) participants, severe for 8 (27%) participants and very severe for 6 (20%) participants.

Of six participants whose spirometry did not meet the criterion for airflow obstruction in COPD, five participants had restrictive or mixed obstructive-restrictive pattern on spirometry. One of these had recorded diagnoses of both COPD and Idiopathic Pulmonary Fibrosis. There was a record of spirometry at diagnosis and within two years for these participants.

One participant was classified with small airways disease on spirometry.

3.4.5.2 Participants with no recorded diagnosis of COPD

Six participants who completed clinical assessments did not actually have a diagnosis of COPD (or equivalent) recorded in the practice records, although GPs had been asked to select participants who met this inclusion criterion.

Four participants who had smoked for many years (mean 51 pack years) did have COPD according to study spirometry.

In one case, the practice record covered only the previous three years and no respiratory diagnosis was recorded. This participant called the breathing problem “emphysema” and was using a short-acting beta-2 agonist occasionally. Spirometry showed COPD was classified as severe (FEV1 45% predicted).

Two participants who were current smokers, had frequent diagnoses of respiratory tract infections recorded (but no diagnosis of chronic bronchitis), despite reporting symptoms of cough, breathlessness and phlegm (in winter and on most days for as long as three months each year) on the study questionnaire.

Asthma was the principal respiratory diagnosis recorded for one participant (ex-smoker, aged 77 years). The participant called it a "breathing problem" and reported breathlessness walking on level ground (MRC grade 3) and cough for at least three months in the winter.

Two other participants had a diagnosis of asthma recorded and their study spirometry did not show fixed airflow limitation.

3.4.5.3 Bronchodilator reversibility

Of those participants with a diagnosis of asthma recorded in addition to COPD (n=18), three (17%) participants had a significant increase in FEV1 post-bronchodilator (> 200ml and ≥ 12%). However airflow limitation was not fully reversible and the post-bronchodilator ratio of FEV1/FVC remained below 0.7.

3.4.6 Basis for diagnosis of COPD

Data extraction was incomplete for some participants, if no transfer of records had occurred when a participant joined the practice after the diagnosis had been made elsewhere. For participants with contemporary records available (n=29), the diagnosis of COPD in 19 (65%) participants had been by a respiratory specialist and in only 10 (35%) participants by a GP. Results of data extraction for these 29 participants are shown in Table 3.4.

3.4.6.1 Symptoms

Prior to diagnosis there had often been multiple consultations for respiratory symptoms over periods from 1 to 10 years. In every case, symptoms typical of COPD had been recorded prior to diagnosis, most frequently cough (90%) and breathlessness (86%). At least two key symptoms (cough, breathlessness, sputum or wheeze) were recorded for 78% of participants. GPs had recorded psychological difficulties at diagnosis in 14 (48%) participants, 7 participants with anxiety and 7 participants with depression.

3.4.6.2 Spirometry

Overall, 23 (79%) participants had spirometry noted in records at diagnosis. Five (50%) GP diagnosed participants had not had spirometry, while 18 (95%) participants diagnosed by a specialist had a test noted in contemporary records. Spirometry results were located for 15 (65%) participants who had spirometry at the time of diagnosis of COPD. The classification of severity of obstruction was moderate for twelve participants and severe for three participants.

3.4.6.3 Other investigations

Radiology of the chest was the most frequently recorded investigation, in 93% of participants, with hyperinflation noted in the result for 63%.

Table 3.3: Comparison of diagnosis in practice records and current spirometry

		Classification on study spirometry				
		COPD	Asthma	SAD	Restrictive/ Mixed	Total
Diagnosis in practice records	COPD	30	0	1	5	36
	Asthma	1	2			3
	Recurrent RTI	2				2
	Nil	1				1

(COPD: FEV1/FVC ratio <0.7, Asthma: post-bronchodilator increase in FEV1 > 200ml and ≥12% and post-bronchodilator FEV1/FVC ≥0.7, SAD = small airways disease: mid-expiratory flow (MEF25-75%) <55% predicted and flow-volume curve configuration convex to volume axis on downward limb, Restrictive/mixed: FVC <80% predicted, FEV1/FVC ratio ≥0.7. RTI = respiratory tract infections)

Table 3.4: Data extraction: results from time of diagnosis for participants with contemporary records available (n=29)

Symptoms and investigations recorded at diagnosis	*n (%)*
Cough	26 (90)
Dyspnoea	25 (86)
Sputum production	23 (79)
Multiple respiratory tract infections	20 (69)
Current smoker at diagnosis	16 (55)
Quit advice given (if a smoker at diagnosis)	12 (75)
Spirometry test	23 (79)
Chest radiology	27 (93)
Steroid trial	7 (24)

3.4.7 Initial management of COPD

3.4.7.1 Smoking cessation

All participants had been smokers for many years prior to recording of the diagnosis and 60% said they were still smoking at that time. In the participants whose records were examined, 75% had a record of advice on smoking cessation around the time of diagnosis.

3.4.7.2 Specialist referral

Referral to a specialist was recorded for 66% of participants.

3.4.7.3 Medication

A steroid trial, either using oral or inhaled corticosteroids for a specified period, was noted in 24% of participants. Treatment with inhaled corticosteroids was commenced in 64% of participants, and for half a reason was documented- either a positive response to a steroid trial on spirometry, reversibility to bronchodilator, a history of asthma symptoms or the patient feeling better during a trial of steroids.

3.4.8 Recent management of COPD

Data from two patients with asthma and no diagnosis of COPD on spirometry were excluded from this analysis.

3.4.8.1 Respiratory symptoms and exercise capacity

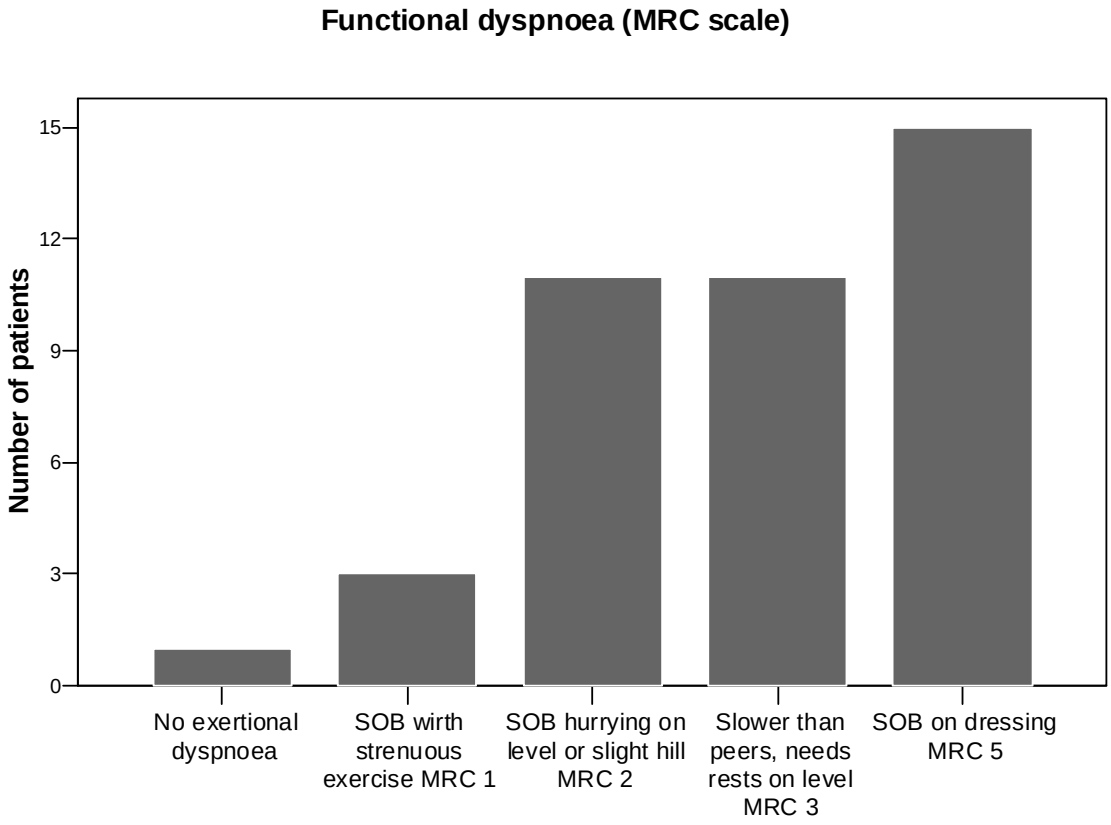
A high proportion of participants reported respiratory symptoms during the previous twelve months, particularly dyspnoea, wheezing, regular winter cough and regular expectoration of sputum (Table 3.5). Three or more symptoms typical of COPD were reported by 59% of participants and at least one exacerbation of their respiratory symptoms over this period was reported by 88% of participants. GPs recorded these symptoms less often than reported by participants.

All but one patient had exertional dyspnoea when questioned. Using the MRC functional dyspnoea scale 37% of participants were classified at grade 4 (breathless on dressing). However, only 52% of participants' records documented exercise capacity or limitations.

Table 3.5: Comparison of data in practice records with participant-reported data for recent symptoms (n=40)

Recent Symptoms	*GP Records (%)*	*Patient response (%)*
Cough	29 (73)	31 (78)
Dyspnoea	32 (80)	36 (90)
Sputum	24 (60)	36 (90)
Wheeze	13 (33)	35 (88)
Respiratory exacerbation	25 (63)	40 (100)
Anxiety	8 (20)	17 (43)
Depression	10 (25)	26 (65)

Figure 3.1: Assessment of functional dyspnoea in participants (n=40)



(SOB= short of breath)

3.4.8.2 Psychological symptoms

A recent record of anxiety was seen for 8 (20%) participants and depression for 10 (25%) participants. However, questionnaires found much higher levels, with 17 (43%) participants likely to have a significant anxiety state and 26 (65%) participants likely to have clinical depression (Table 3.5).

3.4.8.3 Health related quality of life

Scores on the SGRQ indicated there was major impairment of quality of life for all participants with COPD (Table 3.6). The differences in mean scores in those with moderate, severe or very severe COPD were significant for overall scores ($p<0.02$), activity scores ($p<0.01$) and impact scores ($p<0.02$), but not for symptoms ($p=0.25$). The overall, activity and impact scores in participants with COPD were significantly negatively related to FEV1 as a percentage of predicted after adjusting for age. SGRQ scores for participants for whom COPD was not confirmed on spirometry indicated little impairment in the activity or impact domains, but considerable impairment in the symptoms domain.

3.4.8.4 Smoking cessation

Ten participants were continuing smokers, correctly recorded for nine participants, with a record of recent quit advice for six participants.

3.4.8.5 Investigations

Among participants with COPD, there was a record of recent spirometry for 13 (44%) participants and chest radiology for 20 (68%) participants.

3.4.8.6 Medication

The use of medications by all participants that completed a clinical assessment is shown in Table 3.7. Inhaled corticosteroids were being used currently by 72% of participants, either in single inhalers or in a fixed-dose combination with a long-acting beta-2 agonist. There was excellent agreement between prescribing as recorded in notes and patients' responses to questionnaires.

Table 3.6: Health related quality of life for participants with COPD by severity (n=30)

SGRQ scores	*Moderate COPD (n=16)*	*Severe COPD (n=8)*	*Very severe COPD (n=6)*
Overall	40.2 (17.5)	56.0 (19.4)	66.6 (15.7)
Symptoms	59.2 (22.7)	70.3 (20.2)	75.5 (17.8)
Activity	52.4 (22.9)	75.6 (26.9)	87.1 (9.2)
Impacts	24.1 (17.5)	40.3 (17.8)	52.1 (21.1)

Scores presented as mean (SD)

Table 3.7: Current respiratory medication use in all participants completing a clinical assessment (n=40)

Medication	*GP records (%)*	*Patient questionnaire (%)*
Inhaled SABA	35 (88%)	36 (90%)
Inhaled anticholinergic	22 (55%)	21 (53%)
Inhaled LABA	2 (5%)	2 (5%)
ICS	15 (38%)	13 (33%)
Combined ICS/LABA	14 (34%)	14 (34%)
Oral steroid	11 (28%)	11 (28%)

(SABA = short-acting beta-2 agonist, LABA = long-acting beta-2 agonist, ICS = Inhaled corticosteroid)

3.4.9 Qualitative results from focus groups and interviews

A focus group was held in each practice with 16 (84%) doctors participating (10 male / 6 female). Two doctors (male) were interviewed, as they were unable to attend the practice focus group. After an initial short period in which only a few doctors in the groups volunteered answers to an opening question about COPD, all doctors subsequently contributed freely. The atmosphere was open and inquiring with doctors offering views that differed at times from those of their colleagues. The views expressed did not differ systematically between the two practice focus groups, unless highlighted in a specific section. Sometimes apologetic undertones were present, when doctors sensed their clinical practice was not ideal or did not conform to expert opinion or guidelines. The length of time in practice ranged from between five and thirty years for participating doctors. Major themes and sub-themes emerging from analysis of interviews and discussions are described below and supported with examples of quotes from participating doctors.

3.4.9.1 Attitudes of doctors to COPD

3.4.9.1.1 Guidelines

The focus groups were held shortly after publication of the COPDX guidelines (3). Most GPs were unaware of their recommendations, although a few knew the Medical Journal of Australia had published them. Only one GP, who had a training role, was familiar with the guidelines and had found their recommendations useful in clinical practice.

3.4.9.1.2 Diagnosis of COPD

GPs had an appropriate threshold of suspicion for considering the diagnosis in the presence of risk factors:

> *"I would have thought that if someone has been smoking for say 20 years, they are going to have some element of COPD."* (Male GP)

They stated that the diagnosis usually occurs in one of two main ways. The diagnosis was frequently made in hospital as the result of admission for an exacerbation:

> *"I don't suppose it really matters whether one puts a label to it. (A label) sometimes becomes formally attached if they get crook and get admitted to hospital and come back with a diagnosis"* (Male GP)

This GP was also questioning the value of a diagnosis.
The second, less frequent scenario for diagnosis was described as a gradual process and the example below was offered by a GP who disagreed with the first scenario. Recognition of the emerging clinical picture was occurring but without a formal diagnosis being made for some time:

> *" I think you see a lot of people over a period of time who are perhaps in the middle period of life who might have recurrent respiratory infections- smokers. Gradually a picture evolves- patients chronically short of breath, tend to have cough and wheeze, who perhaps benefit from bronchodilators and Atrovent regularly rather than just during exacerbations. I don't know that I agree with (another GP) that diagnosis is always made elsewhere. It's just something that dawns on us after a while"* (Male GP)

However, again in this scenario the usefulness of recording a formal diagnosis was questioned:

> *"It doesn't really matter if you attach a label to it. If you are seeing people repeatedly they usually have other conditions in any case. It just gradually evolves that they have what we call COPD"* (Male GP)

Older GPs noted that COPD was a recent term. They found the changes in terminology used by specialist respiratory groups during their working life confusing and difficult to explain to patients.

> *"From the population point of view changes just confuse them. If you say emphysema, they say 'Oh, that's what you're really talking about!' And people who are getting it in their 40's and 50's hopefully are aware of that too. They won't have heard of COAD, and they certainly wouldn't have heard of COPD"* (Female GP)

Most GPs said they would generally use the term “emphysema” to a patient in preference to “COPD” when they made a diagnosis. They did not feel that patients understood the acronym COPD whereas they were familiar with emphysema. However, because they felt the diagnosis of emphysema had implications for a patient of a serious, ultimately terminal disease, they were reluctant to label the condition:

> *"You don’t actually say they have emphysema, they are not keen to have that. They don’t like emphysema; they have seen Grandad starved of oxygen to death. I find that they will fight that label”* (Female GP)

> *“(COPD) a horrible way to spend the last 10 or 15 years of your life”* (Male GP)

Doctors were not asked direct questions about interpretation of spirometry. However some uncertainty on the spirometry criteria used to define COPD was expressed while seeming to justify not using spirometry:

> *“My understanding is that only in the later stages do you see radiological changes or spirometry changes. And to be doing spirometry on a smoker every couple of years, you are probably not going to see a substantial change”* (Male GP)

3.4.9.1.3 Management of COPD

There was general agreement among GPs that COPD patients were difficult patients to manage. The patients have a chronic condition, often more than one, and come to see a doctor wanting their breathing “fixed” but frequently with attitudes of hopelessness and pessimism. One described their care as:

> *“Palliative care, but over 20 years”* (Male GP)

There was an indication that GPs were nihilistic about treatment for COPD and did not feel there had been any major recent advances in improving outcomes of therapy:

> *(On COPD patients) "They were there winter after winter, after winter, and you think what a horrible way to spend the last 10 or 15 years of your life"* (Male GP)

Doctors said they managed COPD reactively in response to acute clinical changes. They preferred to deal with problems as they arose. There was a lack of structured follow up. They said patients often only visit their doctor when they have an acute exacerbation. They did not believe that regular spirometry would help them manage patients better:

> *" You're responding to a change in their clinical situation… I tend only to do it (spirometry) if there has been some deterioration that the patient noted so that I can compare back with anything else we might have had in the past...but I tend not to do it as a regular thing"* (Male GP)

When prescribing medication, their priority was trying various medications until they found a combination that worked best for the individual. Although a minority used a steroid trial and assessed response with spirometry, they recognized that subjective improvement could occur without objective improvement on spirometry, and they would take this into account, particularly when prescribing inhaled corticosteroids. While recognizing that the ideal approach to managing a chronic disease lay through partnership with patients, they were pessimistic about compliance by patients:

> *"A lot of them don't take their right puffers"* (Male GP)

3.4.9.1.4 Spirometry

They accepted that objective assessments were useful in the diagnosis and management of chronic diseases but GPs drew a distinction between COPD and management of other chronic diseases such as diabetes and hypertension:

> *"I guess blood pressure is really quick, but spirometry is not that quick and there just is not the time to explain it"* (Female GP)

> *"It is a pity we haven't got a test like blood sugar"* (Male GP)

Despite recognizing that radiology has low sensitivity in diagnosing COPD, some GPs said they preferred ordering chest radiographs to spirometry.
They described some operational barriers to using spirometry, difficulties of time, and cost for patients, cost of equipment and lack of access to spirometers:

> *"We need something easy, because otherwise you wouldn't do it"* (Female GP)

> *"GP's are very reluctant to expand their practice in terms of diagnostic equipment, the finances involved are prohibitive"* Male GP)

Almost no doctors performed spirometry personally, irrespective of the type of spirometer owned by the practice and its ease of use or ability to print results that included interpretation:

> *"It is a test that is not often done in general practice. I guess it should be done in general practice, just like we are doing ECGs"* Male GP

GPs admitted to lack of expertise in performing spirometry:

> *"Time is a factor, it is not just the machine. I tried to learn, but I'd forget every time, or you don't program it properly so it doesn't record any data."* Female GP

For GPs in practice 2 whose spirometer was a relatively inaccessible older bellows-type, their preferred model for spirometry testing was specialist or tertiary centre referral. However, they were aware that attending for an investigation outside the practice was a deterrent and patients would often not turn up to appointments if it involved a journey and waiting around in hospital.

3.4.9.1.5 Smoking cessation

GPs said they routinely gave smoking cessation advice to all smokers, but felt COPD patients were a difficult group to motivate:

> *"The percentage of patients diagnosed with COPD that have stopped smoking are far less than those diagnosed with ischaemic heart disease"* (Male GP)

> *"They all imagine that they will have a heart attack or get lung cancer, and they don't think from fifty onwards they will not be able to walk down the street"* (Female GP)

> *"The ones that are still smoking, they don't want to be confronted with a disease (COPD) that goes on apart from your bronchitis, they are not prepared to give up either"* (Female GP)

They were unconvinced that spirometry would help when advising smokers at risk of COPD to quit:

> *"Smoking- the facts are there. I don't think another graph that they have to interpret is going to make any difference. X-rays, if they can see pictures, I think those are quite effective, seeing damaged lungs* (Male GP)

> *"It (spirometry) might make people better aware, but people are aware of not smoking, and they still do"* (Female GP)

They were worried that a normal spirometry result could be taken as a "green light" by smokers to continue smoking:

> *"Perhaps the reverse will work, in that the patient might say my lungs aren't deteriorating on the basis of these tests, so I might just as well keep on (smoking)"* (Male GP)

3.4.9.2 Attitudes of participants with COPD

3.4.9.2.1 Diagnosis of COPD

The preference of participants for using the term emphysema was confirmed in questionnaires, with 28 (67%) participants choosing it in preference to COPD. In interviews, all participants used the term emphysema. However their answers were rarely short and direct. The diagnosis was often qualified with a description of another pre-existing condition, usually asthma:

> *"I had allergy asthma or asthma as a young person, and then I have emphysema which was diagnosed with an X-ray"* (Female, 74)

> *"I had asthma and then, caused through smoking, emphysema" (Female, 60)*

> *"I think it is classed as emphysema but it is basically COPD. Asthma, all that sort of thing it stems from. That is how it started anyway. It started off as asthma. As I got older it progressed onto bigger titles"* (Female, 49)

It was also common for the respiratory diagnosis given to patients by health professionals to be changed:

> *"Well I was originally given the tag of asthma. We were travelling up the east coast of Australia, and as I got further up, my condition got worse. Eventually, by the time we got right up, I think they'd probably diagnosed emphysema and asthma"* (Male, 69)

Patients also used diagnostic terms interchangeably to describe their own symptoms:

> *"Ah, yes, I call it emphysema, but the emphysema has I think brought on the bronchitis, but I've not really had asthma as such. Before the bronchitis sets in I get a lot of coughing, so I mean you could say that it is an asthma attack which then brings on the bronchitis"* (Female, 76)

They also confirmed prolonged withholding of the diagnosis of COPD with eventual disclosure occurring almost incidentally:

> *"Well no one actually told me I had it. Until I went to the doctor one day and they gave me the Atrovent and I said 'This is a new one' and they said 'That is for your emphysema'"* (Female, 50)

Doctors' unwillingness to diagnose COPD and provide information about the illness caused patients to seek information elsewhere, or remain poorly informed:

"I read up in a couple of medical books. I have been like this for two or three years and no one actually told me I had emphysema" (Female, 50)

'I don't really know that much about it. I haven't really had it explained to me" (Male, 55)

3.4.9.2.2 Participants' description of COPD

On the basis of interviews with participants, their responses when talking about the severity of their illness could be divided into three groups (Table 3.8). Emerging groups were formed through initial analysis of the qualitative data without reference to the results of any clinical assessments, which were performed only after the interviews were conducted. The titles of severity groups were drawn from participants' own language. Three participants did not complete the clinical assessments or spirometry tests. For those for whom there was clinical assessment data, the relationship between severity groups and the quantitative data were examined.

Seven participants were grouped under the description of 'COPD as a Life Sentence' and they viewed COPD as frightening, serious and life threatening. Half the group had significant anxiety and depression. Spirometry results confirmed that these participants had very severe COPD, mean FEV1% predicted 23.8 (95% CI 21.1 to 26.6). Their quality of life scores indicated severe impairment, mean SGRQ scores: overall 68.0 (95% CI 52.7 to 83.4), symptoms 75.7 (95% CI 60.5 to 90.8), activities 87.2 (95% CI 76.7 to 97.6), impacts 54.8 (95% CI 34.2 to 75.3).

'A Touch of Emphysema' was the title given to the beliefs of seven participants. They were characteristically more optimistic, and did not consider their respiratory illness a major problem. In comparison with the 'COPD as a Life Sentence' group, only one in this group had clinically significant anxiety or depression. COPD was classified on spirometry as severe for two participants and moderate for four participants, mean FEV1% predicted 53.5 (95% CI 41.1 to 65.9). Mean SGRQ scores were lower (i.e. less impaired) than in the "Life Sentence" group: overall 33.4 (95% CI 14.8 to 2.0), symptoms 52.3 (95% CI 25.6 to 79.1), activities 49.1 (95% CI 18.2 to 80.1), impacts 18.5 (95% CI 6.1 to 31.0).

In the group titled 'Unwilling to rate severity of own illness', there were four participants. Their unwillingness to rate their own severity appeared to be due in some cases to personality traits such as denial, affecting assessment even in the

presence of symptoms with considerable impact on daily life. For three participants who completed clinical assessments, all had scores indicating the presence of clinically significant anxiety and depression. The range of disease severity was wider in this group. On the basis of spirometry, one participant had mild obstruction, and two participants had severe obstruction, median FEV1% predicted 32 (range 25 to 91). Similarly, the impairment of quality of life varied with a wider range of scores; median SGRQ (range) overall: 65.2 (19.9 to 75.6), symptoms 86.7 (56.3 to 97.5), activities 79.1 (13.3 to 93.3), impacts 50.5 (12.3 to 56.7).

Group description	Participants	Meanings	Participant statements
'COPD as a Life Sentence'	7 patients, severely ill when given formal diagnosis, long history of respiratory problems, diagnosis usually made by a specialist after an acute episode	Move away from 'healthy' person prone to short term acute respiratory episodes to a chronically ill person with a life threatening condition. Emphysema seen as frightening and menacing. Expect to get worse	" It is not going to get any better. It is incurable thing emphysema, isn't it? It just gets worse and worse." "I've seen it happen to family members so I don't want it to happen to me, I want to be able to go as long as I can."
'A touch of emphysema'	7 patients, moderately affected, usually diagnosed by a GP, less likely to have been hospitalised. If they have given up smoking they do not expect to get a lot worse	Diagnosis not especially frightening. They do not consider themselves to be really sick. For some the respiratory problems with breathlessness and low energy levels are seen as a normal aspect of ageing (often in addition to other illnesses).	"He (doctor) said no, it won't get worse because I don't smoke no more." "Well I think it is more an age thing, it is all down hill from here." "Well all I can say is I get short of breath. I don't think I've got (emphysema). I've seen people with emphysema. I never look like that"
'Unwilling to rate severity of own illness'	4 patients, variety of diagnostic patterns, some patients express confusion over diagnosis	Overlaid emotional response influencing patients' experience of illness, e.g. feeling depressed and anxious. Need to distract themselves to cope. May be over optimistic or deny implications of disease.	"I don't really know. Doctors have told me it is bad." "Oh, it's that hard to breathe, it's pretty hard, my chest is that tight. It has frightened me a few times." "Well, I hadn't really thought about it (being sick) that much."

Table 3.8: Meaning of the diagnosis of COPD from interviews with eighteen patients

3.4.9.2.3 Patients' beliefs on cause of COPD

Seventeen interviewees discussed smoking, and only one excluded it altogether (Table 3.9). Those who attributed cause to smoking could be divided into three groups for whom it was either the sole factor or a contributory factor in a group in which industrial exposure was also responsible and a group for whom a genetic predisposition of susceptibility to cigarette smoking damage existed. Another group attributed the cause to familial factors, but were not convinced that smoking was a cause. There were no differences between participants in the groups in their current smoking status or smoking history, the severity of obstruction or the proportions with significant anxiety or depression (240).

Notable features among people who explained their illness as resulting from smoking, were their expressions of guilt and self-blame for their poor health and confusion about why other smokers were apparently unaffected. This differed from participants who thought their illness was a result of familial susceptibility or a result (at least partially) of workplace exposure to pollutants. Such participants were better able to avoid feelings of personal accountability associated with an explanation that hinged on choosing to smoke, and to explain why they had become unwell when other smokers had not.

Cause	Participants	Meanings	Participant statements about cause of COPD
'Smoking' Cigarette smoking alone	2 female, 3 males	Why did smoking do this to me and not to all other smokers? Feelings of responsibility, looking for other factors, e.g. medication or stress	"Oh, I'm not fully convinced about it. I am not altogether a believer of the evils of smoking." "Well they say emphysema is caused by smoking. But I don't know. I think a lot of stress. I have got girl friends that smoke. They don't get 'asthma' and they are fit as fiddles."
'Work and smoking' Industrial exposure and cigarettes	3 males formerly employed in manual occupations	Able to explain why smoking did this to them and not all other smokers. No expressions of resentment about dangerous work places.	"Well, it could have been work environment, smoking." "I had been a smoker up until… twelve years possibly before I was diagnosed...and there was a lot of diesel fumes, and petrol fumes.... Whether that added to my problems, I don't know."
'Inherited predisposition and smoking' Genetic susceptibility exacerbated by cigarette smoking	7 females, long history of respiratory problems, some former nurses	Feelings of familial propensity. See themselves as part of a family chain of asthma. Nurses connect smoking and respiratory infections with nursing.	"The smoke. Well, when you work it out, there's people who do like I did. People that don't. Same complaints. It is in the family." "There is a lot of respiratory type stuff in my family, allergies and so forth, and I have a lot of allergies as well."
'Family sickness' Familial illness probably not made worse by smoking	2, female	See themselves as having a family sickness. Unclear about role of smoking, sceptical about advice regarding smoking	"Well unfortunately I've got a family history of it. Yes, I've had two sisters died with emphysema, and my brother also, and another sister died much younger".
Other/Unclear	1 female		Did not talk about cause and smoking enough to place in category

Table 3.9: Causal understanding of COPD from interviews with eighteen patients

3.4.9.2.4 Patients' knowledge about COPD

Knowledge about medications and their purpose was low:

> *"It just sort of clears the airways a bit, I can breath easier. [Interviewer- What do you think goes wrong when they don't (work)?] Wouldn't have a clue"* (Male, 72)

Patients generally said they ought to take their inhalers regularly and felt they helped their symptoms:

> *" You do the best you can with your medicines. You learn to take them at the right time because if you don't, they don't work all that well for you"* (Female, 49)

> *"Because I get wheezy and puff on it. It does help for a little while"* (Female, 50)

Some were not sure that inhaled corticosteroids made any difference:

> *"I don't get a lot of benefit out of what medication I am on. The doctors seem to be quite happy, with the medication I am on"* (Male, 69)

This could reduce their compliance:

> *"I personally don't think that's doing anything at all. I'm no better for it afterwards, and I don't feel any difference, and some mornings I forget to do it"* (Male, 74)

Some worried about asthma medication, visible in spacer deposition, damaging their lungs:

> *I am on Atrovent, Ventolin and Seretide. Three different sprays, I mean you can't tell me they are not staying on my lungs* (Female, 50)

Men were less well informed and often relied on their spouse to manage their medication. Patients' attitudes were related to the severity of COPD. More severely affected patients used multiple medications and spent much time and energy coping with the illness. They were also more likely to have been to pulmonary rehabilitation, but having done so, were more knowledgeable and appeared to cope better. Several expressed frustration that more effective treatment was not available:

> *" I suppose it's grasping for straws, but I'd like to think there was something that I got more benefit out of than I get"* (Male, 69)

3.4.9.2.5 On-going management for COPD

Participants with COPD did not have structured follow-up and consulted doctors infrequently especially if they were less severely affected. They generally visited GPs either for repeat medications:

> *"Only when I have to get a prescription for my medication"* (Female, 61)

or for exacerbation of symptoms.

> *"Urgently if I am really congested, then I do it"* (Female, 76)

Severely affected participants described multiple urgent surgery visits and Emergency Department attendances:

> *"I was going up there more on a regular basis to see doctors. Then it ended up trips in the ambulance from home" (*Female, 49)

3.4.9.2.6 Smoking cessation

All participants discussed smoking cessation, and most participants with severe COPD had actually quit. There was recognition that quitting smoking was not easy but it depended on the circumstances and they knew of severely affected people who had not been able to stop:

> *"That's how I give it up, with no patches or anything. You've got to get it and really persevere"* (Male 72)

> *"I wasn't supposed to smoke anymore but I am a nervy person. I am a worrier all the time and I was smoking as I told the doctor 'I have no other vices'"* (Female 60)

There was an expectation that all doctors would counsel patients to stop smoking:

> *"Well, the doctor told you, you had to give it up. (Wife)" "Any doctor will tell you that"* (Male 72)

> *"Well doctors told me going back a few years ago to stop smoking or I would end up with emphysema blah, blah, blah"* (Female 50)

Participants referred positively to their GP's advice on quitting smoking. Some GPs used a strategy of shock tactics to scare COPD patients. This been effective for one participant:

> *"The doctor told me 'Smoke or die'. So I gave up smokes. That is when I first had an outbreak of emphysema"* (Female, 60)

and another participant unable to quit on their own, felt that it would be effective

> *"If I had a doctor telling me I had to give it up it would give me a bit of a shock. But I just can't tell myself to do it"* (Female, 50)

Participants acknowledged that social, emotional and psychological difficulties might have prevented them from quitting earlier when the damage was not so great:

> *"No, it's not a problem. Not yet at any rate. But I gave up smoking a couple of times, and started up again"* (Male 73)

However, being less aware of the medical evidence of the health risks of smoking and a lower likelihood that a health professional would give them advice to stop were also given as reasons for not stopping smoking earlier.

3.5. Discussion

3.5.1 Significance of results

This study in primary care, that collected simultaneous data on a cohort of patients with COPD from both the patients themselves, their medical records and their GPs, has given a unique insight into current clinical practice in the diagnosis and management of COPD.

3.5.2 Selection of patients with COPD

The study relied for ethical reasons, on the selection of patients with COPD by their GPs. The identification within practices of potential patients suitable for inclusion was through the practice prescribing database alone, as in common with most practices in Australia currently (241) and at the time of the study, the prescribing feature of the electronic patient management record was the most widely used feature (242). When assessed between 1999 and 2002 in Australia, the level of electronic recording of diagnoses was very low compared to electronic recording of prescribing, possibly because software design left optional whether a diagnosis or reason for the prescription was also recorded during the period being studied (242). In the UK, where adoption of computerisation in practices occurred earlier the completeness of electronic recording between 1992 and 1994 varied with the diagnosis, being highest for diabetes and glaucoma but much lower for asthma (243). Both practices that participated used a hybrid records system, consisting of both paper-based and electronic patient records. Among the participants selected by their doctors on the basis of having a diagnosis of COPD, we found some evidence of incompleteness of medical records and errors in GP recollection of diagnosis, particularly in patients with asthma who were long-standing smokers.
However, the study confirmed that in this doctor-selected sample of patients, a doctor-recorded diagnosis of COPD was usually correct according to objective spirometric criteria. There was typically some difficulty in the presence of a possible mixed obstructive-restrictive pattern. This is consistent with the need for more complex lung function testing in the differential diagnosis in this situation (46).

3.5.3 Severity of recognised COPD

Among participants with confirmed COPD, none had airflow obstruction classified as mild at the time of diagnosis and currently although the majority had moderately

severe disease almost half had severe or very severe obstruction. This apparent non-recognition of mild COPD by GPs is consistent with other findings from surveys in general practice (90,97) and population surveys (60,244) in Australia and in the UK (68).

3.5.4 Reasons for lack of early diagnosis

The reasons for lack of recognition of mild COPD appear to be due to a lack of physiological measurements with spirometry, unlike the situation in hypertension where under-diagnosis is more likely to be due to conflicting diagnostic criteria (245). In this group of patients, there was low use of practice-based spirometry for diagnosis. As not all records contained data covering the time of diagnosis, conclusions about diagnostic practice must be made with care, however this finding is similar to that of Soriano et al in a UK study in 1997 which found diagnosis was only supported by spirometry in 38% of patients (246). The quantitative data in this thesis triangulate consistently with the information doctors gave about their clinical practice, which increases their reliability (210). There was also evidence that doctors were ambivalent about the value of spirometry in the diagnosis of COPD. Doctors had a preference for making a diagnosis on clinical grounds, as found in a UK study of GP diagnostic practice in COPD (246). Although this study could not assess the role of under-presentation by patients to their GPs for respiratory symptoms, it did confirm that symptoms suggestive of COPD could be present for long periods without a diagnosis being recorded. If doctors rely on clinical symptoms for diagnosis this may also be a factor contributing to under diagnosis, especially at an earlier stage in the disease.

The operational barriers to performing spirometry reported by doctors i.e. lack of access to reliable spirometers, a low level of expertise in performing and interpreting spirometry, lack of government funding for spirometry testing and lack of time, are all likely to play a role in under-use of diagnostic spirometry.

Lack of diagnostic use of spirometry was compounded by doctors' concerns over communicating to patients a diagnosis of COPD. Delayed diagnosis was consistent with the attitudes doctors expressed during interviews and focus groups. A conscious decision was made not to diagnose COPD in the early stages. This has not previously been reported although a similar attitude was found among 848 general practitioners in Denmark to the diagnosis of lung cancer, where 12% of GPs thought there was no hurry to diagnose the disease and 22% thought diagnostic delay rarely meant

anything for the prognosis (247). Lack of effective therapy was not cited as a reason but doctors' nihilism over promoting smoking cessation did not encourage a proactive approach to case finding. Delay was rationalised by the perception of patients' dislike of the diagnosis. However, delay in receiving a diagnosis from doctors in primary care caused confusion and sometimes distress for patients. A similar reluctance to label patients with COPD was found in a UK study in primary care. Only 36% of patients diagnosed by their general practitioner had ever heard of COPD compared to 79% of those whose first diagnosis was made in hospital by a specialist (248).

3.5.5 COPD management

The picture built up about management of COPD from both patients' and doctor's views, was one of reactive rather than pro-active management, with very little use of spirometry. There was a tendency by doctors to underestimate patients' symptoms, psychological difficulties and limitations. It was apparent that patients generally had poor knowledge of COPD, apart from a minority who had accessed pulmonary rehabilitation and demonstrated better knowledge and coping skills. To what extent doctors' lack of confidence in their own knowledge was responsible for failing to educate patients is not clear.

3.5.6 Smoking cessation and COPD

A marked difference was found between doctors' universal acceptance of smoking as the principal aetiological factor in the development of COPD and a minority of patients who accepted that smoking alone was the cause of their disease. Only four participants described smoking as the principal reason why they had developed breathing problems. Most participants gave multi-causal accounts that emphasised explanatory factors such as a familial tendency to respiratory illness or workplace exposure to pollution. Similar multi-causal accounts of aetiological factors are also given by patients with other smoking related diseases such as ischaemic heart disease (249). Such widespread scepticism among the respondents in this study about medical attempts to link their illness with cigarette smoking may have relevance for the development of smoking cessation interventions for people with COPD. If patients at risk of COPD, or with established COPD, do not consider that smoking is a major factor underpinning the condition they may be less motivated to stop smoking with the aim of improving their respiratory health. GPs may need to elicit

and take into account the perceptions of their patients with COPD and tailor their smoking cessation advice accordingly to acknowledge patients' views.

There was general acceptance among doctors that smoking cessation is the only effective means of preventing progression of early COPD. Doctors perceived that their advice on smoking cessation was relatively ineffective, in contrast to patients' assessment. This false perception by GPs may reduce the frequency of giving patients reminders to quit, despite the known effectiveness of even brief quit advice (143). Other factors that have been found to influence doctors in primary care offering advice on smoking cessation are fear of harming the doctor-patient relationship and wishing to address the patient's agenda preferentially (250). Doctors were not asked questions specifically about smoking cessation but they made a link between demonstrating an abnormality on spirometry and a possible motivating effect on smoking cessation. Their concerns about the converse, whether normal spirometry could be an incentive to continue smoking may be well founded and more evidence is required to answer these questions definitively.

3.5.7 Limitations of the study

To what extent the participants in this study were or are representative of all COPD patients in the practices is not certain. However, participating patients were of similar ages to non-participants in one practice. No data were available on the nature or severity of airways disease in non-participants and it is possible they were systematically different in some way. The participants were all recruited from two practices that had very similar patient populations with a relatively high level of social disadvantage and relatively low levels of educational attainment. However, the experiences and attitudes of people with COPD from different backgrounds with higher levels of education may be different. Many studies show significant associations for prevalence of COPD with lower educational levels (58,251) and with lower socio-economic status (63,251,252). Thus the participants in this study probably represent fairly "typical" COPD patients.

Whether these results are generalisable to primary care throughout Australia is also not certain. With links to an academic department of medicine, the participating practices may not be representative of Tasmanian practices. National guidelines that might encourage more uniform practice had not been long published at the time of this study (3) but other studies have found similar under-recognition of mild COPD both in primary care (253) and in a community sample (254). A follow up study in

these or similar practices after five years from publication of the guidelines would be instructive.

3.5.8 Rationale for intervention study

This preliminary study identified that lack of spirometry in primary care was one contributor to the under-recognition of COPD by doctors. The major barriers identified in it to the performance of more spirometry by doctors in primary care for case finding in COPD were:

- Issues of access to high quality spirometers
- Lack of expertise in spirometry
- Unfamiliarity of GPs with evidence supporting the use of spirometry in the diagnosis and management of COPD
- Doctors' perceptions that spirometry was too time consuming and expensive
- Doctors' fear that smokers would be reluctant to address the consequences of smoking and their concerns that normal results would be seen as legitimising continued smoking.

To investigate the relative importance of the multiple factors potentially affecting the use of spirometry for the recognition of COPD in a primary care setting, a study was designed in which reliable, portable spirometers were provided to doctors, they were given training in performing spirometry and interpreting results, and payment for tests performed. The effect of giving feedback to smokers about their spirometry result on their motivation to quit smoking and smoking behaviour was studied in the practice setting.

Chapter 4

Methodology used for further studies

4.1 Study background

The first stage of this work (Chapter 3) had been to carry out a preliminary study seeking to identify barriers to the diagnosis of COPD in primary care. This had identified a number of potential barriers and to further investigate the importance of the availability of spirometry, an intervention study comparing two alternative models of provision of spirometry was designed.

The study was designed to control for possible confounding variables. Thus, a reliable, accurate and stable electronic spirometer was selected for use in both intervention arms. Primary care health personnel, doctors, practice nurses and practice assistants, who might perform spirometry in practices underwent training in spirometry, to a nationally accepted standard.

4.2 Study hypotheses

From the preliminary study, the following hypotheses were generated and tested in an intervention study:

1. Respiratory-trained nurses, performing spirometry in general practice using a portable spirometer, are an effective way of increasing the frequency and quality of spirometry performed on smokers and ex-smokers aged over 35 years compared with usual GP practice.
2. Performing spirometry on smokers and ex-smokers aged over 35 will facilitate early diagnosis of COPD.
3. Identification of airflow limitation in smokers will act as an incentive for smoking cessation.

4.3 Study design

An intervention study was designed to capture data on all factors thought to be relevant to uptake of spirometry tests in primary care. This includes the acceptability of spirometry tests to patients belonging to the specified target group, the quality of spirometry performed in primary care, GPs' initiation of spirometry testing in clinical practice and GPs' use of spirometry results to make a diagnosis of COPD.

A follow-up study was also included in the design for participants undergoing spirometry performed by a trained nurse in one study arm. The participants in this prospective cohort study were current smokers and the effect of receiving feedback on a normal spirometry result compared to a result demonstrating lung damage was assessed on both intention to cease smoking and change in smoking behaviour.

The intervention study used a practice-level, matched-pair, cluster randomised crossover design, with the practice as the unit of randomisation, since the intervention is based at practice level. Performing research in primary care is not seen as a priority by all GPs (255,256) and our previous experience has shown that the crossover design is associated with improved recruitment of practices. This design was chosen to optimise recruitment. Matched pairing of practices was used to reduce the potential for baseline imbalance in geographical and socio-economic indicators that might be correlated with the outcomes (257).

The two models for spirometry delivery that were compared consisted of a "trained nurse" model (TN) and "usual care" model (UC) for participants belonging to the target group, defined as smokers and ex-smokers aged over 35 years. The TN model involved placing a nurse with portable spirometer in general practice settings, with a brief to facilitate lung function testing of smokers or ex-smokers aged over 35 years. This was compared to a control intervention in the UC model, where an identical spirometer was provided to general practices and utilised according to their usual clinical practice. The comparison of spirometry delivery models was made over the first six-month study period in which the practices were compared as parallel groups, owing to the inevitable crossover effects that would severely bias the frequency of testing in the second period (258).

A cohort of smokers with normal or obstructive lung function on spirometry was recruited throughout the twelve-month study period in all practices during the TN period of spirometry delivery. This cohort was followed up three months later to examine the hypothesis that there were differences in motivation to stop smoking and smoking cessation rates between groups with normal and obstructive lung function.

4.4 Sample size

It was planned to recruit eight practices and it was estimated that 24,000 patients would be seen by all the practices during the study period. Data from only the first allocated period was intended to be used to compare the number of spirometry tests

performed on patients in the target group, as recruitment in the second period would be affected by testing performed during the first period. Two trained nurses conducting spirometry session and performing tests in the four practices allocated to the TN model, were expected to recruit a maximum of 30 patients per week or 1,560 over six months. It was assumed that 25% of patients would refuse to participate, thus calculations were based on providing 1,170 subjects in the TN practices in the first period. Based on previous studies (112), it was expected that general practices would perform 2.9 tests per week, resulting in 301 tests conducted over six months in the UC practices arm.

Data from the 2004 National Drug Strategy, Household Survey indicated that in the age group of 40-49 year olds, the ratio of smokers to ex-smokers would be 47/53. Thus, of the expected 1,170 participants having spirometry in the TN practices in each period, up to 550 current smokers would be recruited for follow up. Based on the results for a control group in a study of the effects of a smoking cessation intervention on stage shift in the Transtheoretical Model, a change of 0.32 (standard deviation 0.78) units for the group with normal lung function was reasonably expected (186). If 1,100 smokers were recruited for follow up, a change of 0.55 units could be detected in pooled 12-month results in the group with abnormal lung function with 80% power at a significance level p=0.05 (257).

4.5 Recruitment of practices

Information about a forthcoming spirometry study and requests for expressions of interest were published in 2004 in the newsletter of the Southern Tasmanian Division of General Practice [Appendix 1a]. The newsletter is distributed to all practices and is available electronically on the division website. In 2004 the Southern Tasmanian Division covered a population of 224,725 people (239). It included 294 GPs in practice and consisted of 94 practices, 74 urban or suburban practices and 20 rural practices. There were 92 practice nurses employed in division practices (259).

Seven practices responded to the newsletter by making contact with the nominated research contact and expressing a willingness to participate; five urban and two rural general practices. One local urban practice was approached directly and after receiving information on the study agreed to participate. Thus eight general practices were included in the study.

4.6 Description of general practices included

4.6.1 Practice One

This was a suburban practice, meeting Australia General Practice Accreditation Limited (AGPAL) accreditation standards (260) and accredited for training by the Royal Australian College of General Practitioners (RACGP). It was involved in undergraduate medical education and was one of the practices that participated in the preliminary study. The practice had eleven vocationally registered general practitioners, three partners and eight associates, working sessions equivalent to seven full-time general practitioners. Two full-time practice nurses were employed. The practice was fully computerised using Medical Director software [Health Communication Network (Limited), NSW] in addition to paper records. Sixty-five consulting sessions were held per week on average, the practice held records on 45,000 patients of whom about 20,000 were considered to be active patients. The practice owned a spirometer, operated normally by a practice nurse who performed tests during occupational medical examinations or for asthma.

4.6.2 Practice Two

This was a rural practice, meeting AGPAL accreditation standards and accredited for training by the RACGP. It was involved in undergraduate medical education and was one of the practices that participated in the preliminary study. The practice had eight vocationally registered general practitioners, working sessions equivalent to six full-time general practitioners. One full-time practice nurses was employed. The practice was fully computerised using Medical Director software. Paper records were phased out at the start the year in which the study was conducted. The practice held records on 20,000 patients of whom about 12,000 were considered to be active patients. Forty-six consulting sessions were held per week on average. The practice owned an old mechanical bellows type spirometer, only used occasionally by the GPs. Patients requiring spirometry were generally referred to a lung function clinic.

4.6.3 Practice Three

This was a suburban community health centre, meeting AGPAL accreditation standards and accredited for training by the RACGP. It was involved in undergraduate medical education. The practice had eight vocationally registered

general practitioners, working sessions equivalent to four full-time general practitioners. There were five part-time practice nurses. The practice was fully computerised and used Medical Director software and paper records. Forty consulting sessions were held per week on average. The practice held records on 40,000 patients of whom about 15,000 were considered to be active patients, though records from practice 7 were also administered from this practice. There was an electronic spirometer used in the practice, operated by a nurse and used approximately twice per week for tests requested by GPs.

4.6.4 Practice Four

This was a suburban practice meeting AGPAL accreditation standards. The practice had four vocationally registered general practitioners, working sessions equivalent to two full-time general practitioners. One full-time practice nurses was employed. The practice was fully computerised and used Medical Director software and paper records. Twenty-one consulting sessions were held per week on average. The practice held records on 5,200 patients of whom about 4,500 were considered to be active patients. The practice owned an old mechanical bellows type spirometer, only used occasionally by a doctor for occupational or diving medical examinations. Other patients requiring spirometry were generally referred to a lung function clinic.

4.6.5 Practice Five

This was a rural practice meeting AGPAL accreditation standards with six vocationally registered general practitioners, working sessions equivalent to three full-time general practitioners. One full-time practice nurse was employed. The practice was fully computerised and used Medical Director software and paper records. Twenty consulting sessions were held per week on average. The practice held records on 10,000 patients of whom about 9,000 were considered to be active patients. The practice did not own a spirometer and patients requiring spirometry were generally referred to a lung function clinic.

4.6.6 Practice Six

This was a city centre practice meeting AGPAL accreditation standards with three vocationally registered general practitioners, working sessions equivalent to two full-time general practitioners. One full-time practice nurse was employed. The practice was fully computerised and used Medical Director software with electronic records

only. Twenty consulting sessions were held per week on average. The practice held records on 7,500 patients of whom about 5,000 were considered to be active patients. The practice did not own a spirometer and patients requiring spirometry were generally referred to a lung function clinic.

4.6.7 Practice Seven

This was a suburban community health centre meeting AGPAL accreditation standards. It was involved in undergraduate medical education. The practice had four vocationally registered general practitioners, working sessions equivalent to two full-time general practitioners. There were two part-time practice nurses. The practice was fully computerised and used Medical Director software in addition to paper records. Fifteen consulting sessions were held per week on average, and the practice records were held with those of practice 2. The practice owned an electronic spirometer, operated usually by a practice nurse to perform tests (less than once a week on average) at the request of a GP.

4.6.8 Practice Eight

This was a city centre practice, meeting AGPAL accreditation standards, with five general practitioners working sessions equivalent to two full-time general practitioners. One full-time practice nurse was employed. The practice was fully computerised using MedTech software [MedTech (Ltd), South Melbourne] and had only electronic patient records. Sixteen consulting sessions were held per week on average. The practice held records on 13,000 patients of whom about 5,000 were considered to be active patients. The practice owned an electronic spirometer used by a practice nurse (once per week on average) at the request of a GP.

4.7 Randomisation of practices

Data was obtained from the 2001 Australian Bureau of Statistics (ABS) census for the postcodes of the practice location (239). Some important social and demographic statistics were extracted. Practices were matched in pairs by geographic location and socio-economic indicators based on the extracted ABS data as summarised in Table 4.1. Practices were then randomised using a random number table.

4.8 Ethical approval and study registration

Approval for the study was sought from The Southern Health & Medical Human Research Ethics Committee, part of the Human Research Ethics Committee (Tasmania) network. Notification of Medical Ethics Approval was received on 5th August 2004: approval number H0007951-The use of spirometry in General Practice: identification and prevention in chronic obstructive pulmonary disease. Approval was maintained throughout the study by the provision of annual reports to the ethics committee.

The study was registered at the Australian Clinical Trials Registry on 18th July 2005, registration number ACTRN012605000006640: A cluster randomised crossover study comparing the efficacy of two models of spirometry provision in general practice on the identification and prevention of chronic obstructive pulmonary disease in smokers and ex-smokers over 35 years.

Practice	*P 1*	*P 4*	*P 2*	*P 5*	*P 3*	*P 7*	*P 6*	*P 8*
Number of active patients	20,000	4,500	12,000	9,000	15,000 (incl.P7)	(incl.in P3)	5,000	5,000
Number FTE GPs	7	2	6	3	4	2	2	2
Geographical location	suburban	suburban	rural	rural	suburban	suburban	city centre	city centre
% ≥ 65 years*	16	19	7	11	18	12	12	11
% < 15 years*	20	18	29	26	18	12	13	15
Median age*	36	41	30	35	41	33	35	35
Median rent/week $*	100-149	100-149	50-99	100-149	100-149	100-149	100-149	100-149
Median household income/week $*	600-699	700-799	500-599	600-699	600-699	400-499	700-799	700-799
Mean household size*	2.3	2.4	2.8	2.7	2.4	2.6	2.1	2.1
% unemployed*	12	6	16	11	9	20	8	8
% qualification post-year 12*	24	29	13	20	20	10	40	37

Table 4.1 Description of paired practices and population in the practice location
(* data from ABS census 2001 for practice postcode. Paired practices shown in adjacent columns).

4.9 Setting up the study in practices

4.9.1 Initial contact with practices

In September 2004 a letter was sent to the GPs at each practice giving them details of the two six month study intervention periods, detailing what was required from the practice before commencing the study and during each intervention period [Appendix 2b]. A visit to each practice was made to explain the study to practice administrative staff, introduce the research nurses who would be visiting regularly during the twelve month study and provide the software for the electronic spirometer used in the study for installation on practice computers. A suitable date and time for spirometry training was arranged for each practice during the visit.

4.9.2 Practice consent to participate

General practitioners were asked at the time of recruitment for their consent to review of their practice notes for any patients enrolled who gave their consent.

4.9.3 Study information for use within practices

Practices in the TN spirometry model were provided with a poster for display, informing patients of the availability of lung function testing for those aged over 35 years who were smokers or ex-smokers [Appendix 3]. Another poster was supplied for display during the times the trained nurse was conducting spirometry sessions [Appendix 4] and a notice to remind receptionists to offer the study information and questionnaire to all patients coming into the surgery the if they were over 35 years and had ever smoked regularly [Appendix 5].

4.9.4 Spirometry Training

An educational session on spirometry was conducted in each practice between October-November 2004. Training lasted between two to three hours and was given by a respiratory physiologist and a specialist respiratory physician. Topics covered included; indications for spirometry, correct performance of spirometry and interpretation of spirometry results. There was an emphasis on the role of spirometry in confirming the diagnosis of COPD. The electronic spirometer used in the study was demonstrated and each participant was given the opportunity to use the spirometer and observed performing a spirometry test. The course materials were adapted from those used extensively previously in spirometry training in Monash

University by co-investigators. The respiratory physiologist was the author of a book on spirometry in clinical medicine (46) aimed at health professionals working in primary care.

4.10 Materials and measures

4.10.1 Spirometry

4.10.1.1 Spirometer selection

The spirometer selected for use in the study, the EasyOne™ (ndd Medizintechnik AG Technoparkstrasse, Switzerland) is a handheld model utilising an ultrasonic sensor to measure flow. Selection was based on mode of operation, accuracy and stability. It is claimed by the manufacturer that, except in the case of structural damage, the EasyOne will maintain its accuracy throughout its operational life and therefore will not require regular calibration. The EasyOne measures respired gas velocity from the transit-time of bi-directional ultrasonic pulses directed diagonally across the gas stream. Flow is computed from the measured gas velocity and known cross-sectional area of the gas stream and volume is obtained by integration. As the EasyOne has no moving parts, the accuracy is not dependent on mechanical function, nor is it dependent on the measurement of variables such as pressure or volume. Providing the cross-sectional area of the gas stream is fixed, the only variable requiring accurate measurement is the transit-time of the ultrasonic pulses between the two transmitters and receivers.

Six EasyOne spirometers were purchased for use throughout the study at a cost of $14,100.

The spirometer uses a disposable mouthpiece assembly (spirette™) consisting of a biodegradable polyethylene tube inserted into the device and through which the subject performs the spirometry test or the operator performs the calibration check. The disposable spirette acts only as a hygienic shield and is transparent to the ultrasonic pulses travelling between the measurement transducers. Since the disposable spirette has no sensor elements, it does not perform a measurement function and therefore does not require calibration. Practices and trained nurses were supplied with spirettes for use during the study, at an approximate cost of $2.40 each.

4.10.1.2. EasyOne Specifications

Dimension 83 x 158 x 43 mm

Weight 245 g

Measuring accuracy	Volume: ± 2% or 0.050 l
	Flow: ± 2% or 0.020 l/s
	PEF: ± 5% or 0.200 l/s
	MVV: ± 5% or 5 l/min
Resolution	Volume: > 1 ml
	Flow: 4 ml/s
Measuring range	Volume: ± 12 l
	Flow ± 16 l/s

Resistance approx. 0.3 cm H2O/l/s

Display 64 x 160 pixel graphic display

Data entry 14-key keyboard

[Appendix 6: full specifications]

4.10.1.3. Predicted normal values for spirometry

The predicted normal spirometry values selected were based on data from a study published in 1976 by Knudsen et al (261). This has an age range from 8- 85 years, a height range from 110-220 cm and is derived from a Caucasian ethnic group. Parameters compared and reported are FVC, FEV1, FEV1/FVC, $FEF_{25-75\%}$ and PEF. In the case of patients from other ethnic groups (Asian, African, Hispanic or Aboriginal) a correction factor of 88% was applied. For patients over 85 years of age, the predicted reference set used was that of Crapo et al (262).

4.10.1.4. Performance of spirometry

A test consisted of three acceptable blows, performed without bronchodilator administration to reduce testing time and to minimize refusals. A previous study found the commonest reason for refusing spirometry was objecting to the use of inhaled bronchodilator to test reversibility (121). The standard required for spirometry performed in both TN and UC spirometry delivery models was defined by the contemporary criteria of the American Thoracic Society (ATS) in 2004 (225) and all tests were compared against these criteria.

4.10.1.5 Use of the EasyOne spirometer for testing

The EasyOne was used in diagnostic mode and FVC-expiration was selected as the test type. After patient data were entered into the keyboard, a spirette was inserted. The operator pressed ENTER when the patient was ready, holding the spirometer still while the sensor set the baseline. A screen prompt BLAST OUT and audible signal indicated the spirometer was ready for use. At the end of each patient expiratory manoeuvre, a message appeared on the screen indicating whether it was acceptable. At least three acceptable, reproducible manoeuvres had to be performed before the message SESSION COMPLETE appeared on the screen.

4.10.1.6 Spirometry quality prompts

The EasyOne spirometer incorporates quality prompts based on the ATS criteria for acceptable quality spirometry (225). If the back-extrapolated volume exceeds 150ml or 5% a screen message DON'T HESITATE appears. If the time until peak flow is greater than 120ms, the message BLAST OUT FASTER appears. If the expiration time is less than two seconds or volume accumulation has not dropped below 100ml per 0.5 seconds, the message BLOW OUT LONGER appears. If the difference between FVC or FEV1 best test is greater than 150ml there is a message DEEPER BREATH. Once three acceptable tests have been performed the screen displays TEST COMPLETE.

4.10.1.7 Spirometry quality grading

The EasyOne automatically grades each completed spirometry test into the categories:

Grade A= three acceptable tests and difference between best two FEV and FVC =<150 ml;

Grade B= three acceptable tests and difference between best two FEV and FVC =< 200 ml;

Grade C= two acceptable tests and difference between best two FEV and FVC =< 250 ml;

Grade D= at least two acceptable trials but results not reproducible or only 1 acceptable trial;

Grade F= no acceptable test available.

In order to assess the adequacy of testing to provide a result that could be used by a GP for the diagnosis of COPD, spirometry results were dichotomised into: “Good” (grades A-C) or “Poor” (Grades D or F).

4.10.1.8 Spirometry reports

EasyOne automatically stores more than 700 test sessions (patient data, test results, and curves). A connector cable supplied with each EasyOne enables results to be downloaded to a PC database using EasyWare V2.6. Individual reports were printed via a linked printer showing the best three test values and curves. The best value for lung function parameters was selected to compare with predicted values. Reports were printed without an automatic interpretation or “lung age” [Appendix 7].

4.10.2 Interpretation of spirometry results

4.10.2.1Algorithm classification

An algorithm was developed for use in the study, against which the spirometry result was compared in order to classify results. The nurse applied the algorithm to all spirometry tests and recorded the classification. A specialist respiratory physiologist also classified each spirometry test independently using the algorithm. The level of agreement between both classifications was tested. Classification by the algorithm was used for spirometry results from both TN and UC practices to identify participants for follow up with extraction of results from practice records.
The algorithm divided results into three categories.

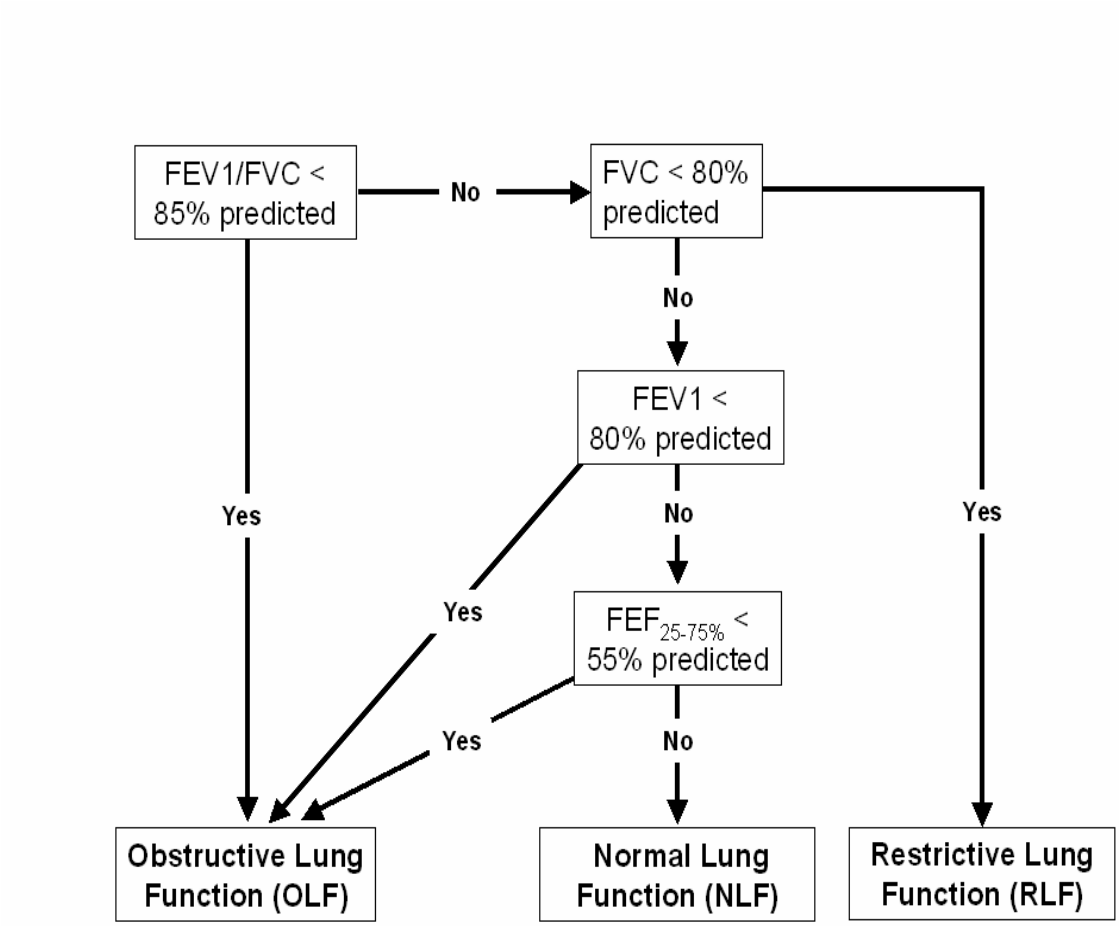
1. Obstructive lung function (OLF): Airflow limitation defined as FEV1/FVC <85% predicted, which allows for the changes in FEV1/FVC which occur with age (43), or maximum expiratory flow rate at 25-75% of vital capacity ($FEF_{25-75\%}$) <55% predicted, as an index of small airways damage (41).
2. Restrictive Lung Function (RLF): FEV1 < 80% predicted, FEV1/FVC > 85 % predicted.
3. Normal lung function (NLF): FEV1/FVC ≥ 85% of predicted normal and FEV1 >80% predicted.

The criteria for OLF were based on those used in a community-based population study of early detection of COPD carried out in Poland (191) that defined COPD using the ERS guidelines (12). The target population in that study included over 40 year olds with a smoking history of at least ten pack years. The criteria for RLF were

based on a combination of those used in the same study to classify a restrictive or mixed restrictive-obstructive pattern of ventilatory impairment.

It should be noted that although the study aimed to provide an accurate physiological assessment as possible, the algorithm was used to select participants for follow-up for both data extraction from practice records and follow-up of smoking cessation in those who were current smokers. In the latter situation, the actual accuracy of diagnosis was not critical. The feedback message to the patient comprised the differential variable. GPs were not provided with the algorithm when interpreting spirometry results.

Figure 4.1: Spirometry interpretation algorithm



4.10.2.2 Classification of airflow obstruction (AO)

Participants were also identified by the more robust definition of airflow obstruction (AO) based on a ratio of FEV1 to FVC less than 0.7. This value of the post-bronchodilator ratio of FEV1/FVC is specified in major guidelines for the diagnosis of COPD (3,10,11,13,15).

4.10.3 Calibration of spirometers

Calibration checks were carried out using a calibration syringe (Hans Rudolph, USA) with a certified accuracy of ±0.5% to deliver 3.00 litres of room air through the spirometer (expiratory calibration check) then withdrawn back into the syringe (inspiratory calibration check). Operators were instructed to empty, then fill the syringe within 6 seconds. The volume measured by the spirometer and the mean flows generated during calibrations were recorded. To meet the accuracy requirements, the volume recorded by the spirometer using a 3.00 litre syringe should be within the range 2.895-3.105 litres (225).

Trained nurses performed calibration checks weekly on two spirometers used during spirometry sessions in practices during the TN period. The nurses visited each UC practice to perform a calibration check at least monthly during the UC period of spirometry delivery. Results for calibration checks were downloaded monthly from each spirometer to a PC database using EasyWare V2.6.

4.10.4 Calculation of smoking pack year exposure

A calculation of consumption of tobacco products was made based on the "pack years of cigarettes, or the equivalent thereof in other tobacco products ". On this basis, one pack year of cigarettes is equivalent to 20 tailor made cigarettes per day for a period of one calendar year. Thus, the number of pack years for a current smoker was calculated from the formula:

(Year of recruitment - Year starting smoking) x Number of cigarettes smoked per day ÷ 20

The number of pack years for an ex-smoker was calculated from the formula:

(Year ceased smoking - Year starting smoking) x Number of cigarettes smoked per day ÷ 20

One tailor-made cigarette approximates to one gram of tobacco or one gram of cigar or pipe tobacco by weight. Thus, one pack year of tailor-made cigarettes or 7300

cigarettes equates to 7.3kg of smoking tobacco by weight. The calculation for users of other tobacco products such as pipe tobacco was made as follows.

[Weight of tobacco smoker per week (gms) x 52 ÷ 7300] x (Year of recruitment - Year starting smoking)

or

[Weight of tobacco smoker per week (gms) x 52 ÷ 7300] x (Year ceased smoking - Year starting smoking)

4.10.5 Calculation of nicotine dependence in current smokers

4.10.5.1 Daily number of cigarettes smoked

The raw number of cigarettes smoked per day was used as one measure of nicotine dependence.

4.10.5.2 Heaviness of Smoking Index

The heaviness of smoking index (HSI) was also used to measure addiction in current smokers. This is a two-item measure derived from the Fagerström Tolerance Questionnaire (FTQ) (263). This eight item questionnaire covers the time of first cigarette, difficulty refraining from smoking, missing a cigarette, the number of cigarettes smoked per day, early morning frequency of smoking, smoking when ill, nicotine yield of cigarettes and inhalation. It has been reduced in the HSI to the items:

1. How many cigarettes/day do you smoke?
- 10 or less = score 0
- 11-20 = score 1
- 21-30 = score 2
- 31 or more = score 3

2. How long after waking do you have your first cigarette?
- Less than 5 minutes = score 0
- 6-30 minutes = score 1
- 31-60 minutes = score 2
- More than 60 minutes = score 3

The scores range from 0 (least dependent) to a maximum of 6 (most dependent).

The method of scoring information on the number of cigarettes a day and the time to first cigarette is based on the relationships with the biochemical indicators of smoking, alveolar carbon monoxide and cotinine (264).

The HSI is valid and reliable. It has good internal consistency when compared to a modified FTQ, with alpha coefficients of 0.72 and 0.70 and test high -retest correlation r=0.87 ($p<0.001$). The HSI is strongly associated with salivary cotinine ($p<0.001$) (263).

4.10.6 Stages of change for smoking cessation

Current and former smokers were classified as being in one of the five stages of the Transtheoretical Model (TTM) of Prochaska and DiClemente (161).

6. Precontemplation: a smoker is not thinking about quitting smoking in the next six months.
7. Contemplation: a smoker is seriously thinking about quitting in the next six months
8. Preparation: a smoker has tried to quit smoking in the past 12 months and is seriously think about quitting in the next 30 days.
9. Action: a smoker has ceased smoking within the past six months.
10. Maintenance: a former smoker has not smoked for at least six months.

4.10.7 Self efficacy towards quitting for current smokers

Self-efficacy is known to be associated with adoption of many health behaviours including smoking cessation (265). A 12-item questionnaire measuring self-efficacy of current and former smokers has been developed and validated from questionnaires used in single studies (181). It has two six-item subscales measuring confidence in ability to refrain from smoking when facing internal stimuli (such as feeling depressed or nervous) or external stimuli (such as after a meal or being with smokers). However, this questionnaire was considered too long to be used in the setting of an opportunistic study. A significant association was found between each of the twelve items, composite scores for internal and external stimuli and the confidence of smokers in their ability to quit smoking using a 4-point scale (181). Thus, self-efficacy towards quitting was measured using the following single question with four possible responses:

How confident are you that you could stop smoking completely if you decided to?

Not confident/a little bit confident/quite confident/very confident

4.10.8 Other cognitive factors affecting smoking cessation behaviour

Information was collected on other cognitive factors known to affect behaviour change. Factors consisting of beliefs about the perceived advantages and disadvantages (outcome expectations) as incorporated in Bandura's social cognitive theory (155) were assessed using questions on belief about the advantages of stopping smoking and self-assessment of present comparative health status. These had been used previously in a study investigating factors influencing readiness to quit smoking (175).

1. How important in your opinion are the benefits to stopping smoking for someone of your age?
2. How do you rate your present state of health relative to others of your own age?

A third question on belief about the effect of smoking on lung health was also included (266).

3. How likely is it that your lung health has been adversely affected by your cigarette smoking?

These questions were answered using a visual analogue 0-100mm scale (VAS) by asking the respondent to mark with a cross the position of their rating. The outer limits were marked to indicate a range from "much worse than average / not at all likely / not at all important" to "much better than average/ very likely / very important".

A cognitive factor assessing the influences that individuals experience from the social system in which they live (179) was assessed using a question about the influence of significant others (175):

4. How much do people among your close family or friends want you to stop smoking?

A 4-point scale was used for answers: none/a little/some/very much.

4.10.9 Measurement of smoking cessation

Selection of the outcome measure for smoking cessation was made in the light of the research hypothesis that identification of airflow limitation in smokers will act as an incentive for smoking cessation. It was felt that the potential effect was best assessed through immediate and intermediate goals as measured by point prevalence abstinence (183). Point prevalence abstinence rates reflect the percentage of former

smokers who are not smoking with a specified period of abstinence. The 24-hour abstinence period was selected as sensitive to the early effects of the intervention. A longer abstinence period of at least seven days was also used to define a non-smoker and measure point prevalence three months following spirometry. The number of cigarettes per day being smoked three months following spirometry was also measured.

Self-report was used to measure smoking prevalence and cigarette consumption. The intervention of spirometry with communication of the result immediately by a nurse, fits the definition of a "minimal interaction study" as classified by Velicer (183) who suggests that it is likely that there will only be low false reporting of smoking cessation. Although this has the potential for misrepresentation of status compared to biochemical validation measures, under the circumstances of opportunistic spirometry testing it was desirable to make follow up procedures simple to decrease the drop out rate. The bias towards over reporting of abstinence for self-report compared to biochemical validation of status was found to be small, affecting 3% to 5% of participants, in the Lung Health study (267).

Any participant lost to the three-month follow up was regarded for analysis as a continuing smoker.

4.10.10 Demographic variables

The current age, date of birth and gender were recorded for each participant. Marital status (single/married or living with partner/widowed or divorced) and level of education using the Australian Standard Classification of Education (ASCED) levels and definitions were recorded for smokers.

4.10.11 Measurement of respiratory symptoms and functional limitation

The Medical Research Council (MRC) dyspnoea scale has been developed to grade the effect of breathlessness on daily activities (268). It measures perceived respiratory disability and allows patients to indicate the extent to which breathlessness affects their mobility. There is a relationship between MRC dyspnoea grade and functional tests, such as walking test performance (269).

Four questions were used to classify participants into grades 1-4.

1. Do you get breathless with strenuous exercise?
2. Do you get breathless when hurrying on the level or walking up a slight hill?

3. Are you slower than most people of your age walking on the level or do you have to stop for breath walking at your own pace on the level?
4. Do you have to stop for breath if you walk 100 metres or after a few minutes?

4.10.12 Use of respiratory medications

The current use of inhaled respiratory medications was recorded, and respondents were asked to provide names of inhalers if used.

4.10.13 Measurement of existing respiratory disease

The diagnosis of "any lung condition" by a doctor was recorded, with specific recording of asthma, chronic bronchitis, emphysema, chronic obstructive pulmonary disease or another named condition.

4.10.14 Acceptability of spirometry to participants in TN practices

Participants recruited in TN practices read a brief description of how lung function is measured at the beginning of Questionnaire A and were then asked to respond to the question "Would you like a spirometry test?"

If the response was positive, they were asked to indicate their reasons from a list of possible reasons or explain their reason in their own words.

1. Check up?
2. Like to know my lung function?
3. Worried about my lungs?
4. Doctor asked me to have one?
5. Saw a poster in the waiting room?
6. Family or friend asked me to have one?
7. Other reason

If the participant responded negatively to the offer of spirometry, they were asked to indicate their reasons from a list of possible reasons or explain their reason in their own words.

1. Not interested in knowing
2. Result might worry me
3. Do not like having tests
4. I think my lungs are OK
5. Other reason

Multiple positive or negative responses were possible.

4.10.15 Qualitative outcomes

4.10.15.1 Choice of focus groups for qualitative research method

Focus groups were selected as being most suited to the investigation of the advantages of different models of spirometry provision in practices. They were used to explore the experience of spirometry in practices and the impact on the practice from both clinical and organizational viewpoints with doctors and any other key informants including practice nurses and practice administrators. This approach was practical within a limited a time frame that did not disrupt normal practice functioning (206). The group interaction was thought advantageous, with the potential for a more complete discussion of issues from all aspects and for an examination of differences between doctors' experiences. The ability to pre-set the agenda and parameters for discussion using in the same format in each group increases the validity of findings (214).

4.10.15.2 Collection of data

Focus groups were held at each of the eight participating practices at the completion of the first six-month intervention period. The time and date was selected to enable the maximum number of doctors and practice nurses in each practice to attend. The most suitable time was determined with the practice manager after consultation with doctors. Each participant gave written informed consent to participate.

I participated in each focus group with at least one other researcher (ECH, CC, JG) and took one of two roles on different occasions. These roles consisted of acting as either a facilitator (to guide the discussion using a prepared list of open-ended questions) or a note-taker (to record the order of participants speaking and any non-verbal contextual information) (206). The facilitator briefed participating GPs before any discussion commenced, on the expectations of confidentiality, voluntary participation and avoidance of disagreement with the views of others. The aim of the facilitator was to guide discussion on the topic without being over-directive, and to be respectful and non-judgmental (270). Clinical scenarios were used to stimulate discussion on how spirometry was used in specific situations. The cases were an anonymous male and female, both current smokers, drawn from study results (Appendix 13). One was an example of typical moderate COPD. In the other case, breathlessness was noted as a symptom and the spirometry was consistent with small

airways disease in which the forced expiratory ratio did not meet the criterion for COPD. Discussions were audio taped.

Verbatim transcripts were made as soon as practicable after each focus group, either by me or another researcher who had been present. I read all transcripts immediately after transcription to check their accuracy, which was double-checked by the second researcher present at the focus group.

4.10.15.3 Choice of qualitative research analytic framework

An iterative thematic method of data analysis was chosen (198) as the framework as the purpose of the qualitative component of the study was to contribute to a full evaluation of the models of spirometry delivery (271). This does not preclude a subsequent conceptual analysis of underlying themes (202) though this does not form part of this thesis. As interview data were collected through focus group discussions, they were read and re-read while emerging themes were noted (196). The initial step consisted of open coding using a comprehensive examination of the data looking for codes in three pre-specified areas:

1. Comparison of effectiveness of the models of spirometry delivery in primary care
2. The use of spirometry
3. Diagnosis of COPD.

The analysis was not restricted to these issues. During the coding process there was an effort to maintain an open attitude to the data and other issues and ideas were noted as analysis progressed. These could be differences or similarities between events, actions and interactions (201). Labels were applied to codes in this first stage. Codes were compared, sorted and connections made between them to develop axial codes (201). Frequently occurring core categories or themes were noted (204). Emerging themes were verified by a second researcher experienced in qualitative research who had participated in facilitating the focus groups. Memos were written regularly during the process of analysis when codes were identified and following coding sessions. These maintained a record of the development of themes, separate from the data and provided a descriptive record of ideas, insights and hypotheses (201).

The emergent themes were compared between focus groups composed of doctors who had experienced the either the TN or UC spirometry delivery model, noting those that were common to both and where differences were apparent.

The combination of qualitative and quantitative research methods in the intervention study was used in order to contrast the qualitative findings with the principal quantitative results of spirometry performance in both spirometry delivery models in order to evaluate and interpret those results (210,211).

4.10.15.4 Software for qualitative analysis

Qualitative data were analysed using NVivo (version 2, Qualitative Solutions & Research International, Melbourne, Vic) for data storage and manipulation during coding for retrieval, linking, shaping and theory generation.

4.10.16 Data extraction from practice record

In order to examine the use of spirometry results made by doctors, practice records of selected participants were reviewed and data was extracted and entered into a template by the researcher [Appendix 8: Data extraction template]. Both paper records and electronic records were reviewed and the nature of the source of data was recorded.

Data was sought on the following items:

1. Number of consultations: 3 months pre-spirometry/ 3 months post-spirometry
2. Diagnosis in summary: 12 months pre-spirometry / 3 months post-spirometry
    a. Asthma
    b. Chronic bronchitis
    c. Emphysema
    d. COPD
    e. Interstitial lung disease
    f. Other respiratory disease
3. Medications prescribed: 12 months pre-spirometry / 3 months post-spirometry
    a. Short-acting $beta_2$ agonist
    b. Long-acting $beta_2$ agonist
    c. Inhaled corticosteroid
    d. Combination inhaled corticosteroid/ Long-acting $beta_2$ agonist
    e. Inhaled anticholinergic
    f. Tiotropium
    g. Theophylline
    h. Influenza vaccination
    i. Pneumococcal vaccination

   j. Other respiratory medication
4. Recorded of smoking status: 12 months pre-spirometry / 3 months post-spirometry
   a. Current
   b. Ex-smoker
   c. Non-smoker
   d. Not recorded
5. Recording of smoking cessation advice (if applicable): Post-spirometry only
   a. No
   b. Yes
6. Recording of smoking cessation assistance (if applicable): Post-spirometry only
   a. Referral to smoking cessation clinic
   b. Prescribe nicotine replacement therapy
   c. Prescribe bupropion
   d. Other assistance
7. Spirometry repeated
   a. By GP without bronchodilator reversibility
   b. By GP with bronchodilator reversibility
   c. Referred to lung function clinic
   d. No record
8. Referral to respiratory specialist
9. Referral for chest radiology
10. Referral for pulmonary rehabilitation
11. Recording of physical activity/limitation
12. Recording of respiratory symptoms
13. Recording of exacerbation

The time taken to extract the data was recorded.

4.11 Procedures

4.11.1 "Trained Nurse" model

4.11.1.1 Recruitment of individual participants

Initial contact with participants was opportunistic, with the aim being to approach every patient attending the practice during a spirometry session and request their participation if they belonged the “target group”, being over 35 years of age and a

regular smoker of tobacco, currently or in the past. The practice receptionists offered an information sheet (Appendix 9: Patient information and consent) with the initial questionnaire (Appendix 10: Questionnaire A) as patients arrived. The visiting trained nurse also asked practice patients sitting in the waiting areas to participate during any breaks in testing. Individual practice patients who did not wish to have a spirometry test were requested to complete Questionnaire A as far as possible and no further contact with these participants was made.

Trained nurses were also available to perform spirometry if requested by the GP on any patient. Unless the patient was in the target group, no additional study procedures were carried out.

Practice patients who attended on other days were also recruited through posters informing patients about the study, recommendation of the GP or another health professional. If they completed the initial questionnaire and provided their contact details, the trained nurse would make telephone contact and offer an appointment for a suitable time to attend for full enrolment.

4.11.1.2 Consent

Each spirometry test on a participant in the target group commenced with a verbal explanation of the study given by the trained nurse and review of the written information sheet (Appendix 9). If the patient consented to participate and undergo spirometry they were asked to sign the attached consent form. A signed copy of the consent form and the information sheet was given to each participant. A signed consent form was retained for each participant.

4.11.1.3 Questionnaire A

Each participant recruited in the target group completed this in the waiting room. They were checked for completeness by the trained nurse prior to testing for those who agreed to spirometry [Appendix 10].

4.11.1.4 Spirometry

In order to exclude any participant for whom there might be a risk of an adverse effect from performing spirometry, the trained nurse asked three safety questions and excluded any with a positive response. These potential participants were invited to enrol after the required waiting period had elapsed.

1. Have you had major surgery in the past six weeks- eye, abdominal, chest, brain or other?
2. Have you had been in hospital with a (heart attack) myocardial infarction or severe angina in the past six weeks?
3. Do you have abdominal pain, nausea or diarrhoea?

A measurement of the participant's height was obtained using a measuring device previously checked for accuracy. Patient details were entered into the spirometer. The breathing manoeuvres required to perform a test were described in detail and demonstrated, emphasising complete exhalation (Figures 4.2, 4.3, 4.4).
Testing was continued until three acceptable tests had been performed or until the patient declined to continue. The number of attempts was recorded. Upon satisfactory completion of the test, the nurse viewed the results and compared them to the study algorithm. The time taken to complete the test was recorded from the time after consent to participate was obtained until after communication of the result to the participant. This included asking safety questions, measuring height and weight, performing expiratory manoeuvres, classification of the result against the algorithm and feedback to the participant.

Figure 4.2: The trained nurse demonstrates the EasyOne spirometer while describing the breathing manoeuvres to be used

Figure 4.3: The trained nurse demonstrates full inspiration while coaching a subject during spirometry.

Figure 4.4: The trained nurse demonstrates full expiration while coaching a subject during spirometry.

4.11.1.5 Feedback of spirometry result to participant

The result of classification was communicated to the participant immediately after testing. The trained nurse presented and gave feedback on results to participants. Participants with normal lung function (NLF) were informed that there was no evidence of damage to the airways at the moment and GP follow up was not suggested unless the participant required further explanation or sought advice on smoking cessation.

Participants with obstructive lung function (OLF) were informed that there was evidence of some changes or damage in the airways, most likely related to smoking. They were requested to make an appointment with the GP to follow up the results.

Participants classified with restrictive lung function (RLF) were informed there was evidence of some change in lung function but this was probably unrelated to smoking. Follow up by the GP was advised for the participant to receive further explanation and investigations or advice on smoking cessation. A restrictive ventilatory defect suggested by spirometry results, requires formal measurements of lung volumes for confirmation and quantifying (46).

4. 11.1.6 Report to GP

All spirometry results were printed via a printer linked to a PC in the research office. They were faxed to the participant's practice within 48 hours of testing. Printed results were de-identified apart from the study identification number and retained for assessment of quality and comparison of classification by a respiratory physiologist.

4.11.1.7 Brief smoking cessation advice to current smokers

It was decided that ethically in the best interests of participants, all current smokers should be counselled on the importance of smoking cessation. A systematic review of studies using minimal intervention by a physician, defined as a brief stop smoking message with or without printed materials, found it was effective in increasing the rate of smoking cessation, odds ratio 1.74 (95% CI 1.48 to 2.05) (143).

After being notified of the spirometry result, the same brief clear message was given to any participant who was a smoker.

"It is important for you to quit smoking now and you can find help in the Quit booklet".

A booklet published for Quit Tasmania covering the topics: deciding to quit, getting ready to quit, quitting, staying a non-smoker and coping with setbacks and including a telephone number for seeking assistance, was given to all current smokers.

4.11.1.8 Follow up spirometry result: smokers

4.11.1.8.1 Questionnaire B

Participants who were current smokers completed Questionnaire B (to collect additional demographic data and retest attitudes to health and smoking and stage of change) immediately after receiving feedback on their spirometry result. If time did not permit immediate completion, it was returned by mail in a postage-paid envelope [Appendix 11].

4.11.1.8.2 Questionnaire C

Questionnaire C was sent to participants who were current smokers three months following spirometry for self-completion, with a postage-paid envelope supplied for its return [Appendix 12]. If it was not returned within two weeks, attempts to make contact by telephone were made and if successful the questionnaire administered by telephone. If phone contact was unsuccessful, a repeat questionnaire was sent to the address supplied at recruitment. A minimum of three attempts was made to contact each participant before classifying them as lost to follow up.

4.11.1.9 Focus group follow up of spirometry model

A focus group lasting 90 minutes was scheduled with each participating practice after completion of the first six months. All doctors, practice nurses and practice managers were invited to attend. Groups met at the practices premises, normally outside consultation times. The facilitator greeted participants, while refreshments were served as they gathered. The facilitator commenced with an overview of the study, an explanation of the conditions that applied to the discussion: confidentiality, anonymity, and the right to withdraw or not to answer a question. All participants were asked to sign and consent form and permission was sought to turn on a tape recorder. A recording was made using a multi-directional microphone situated centrally on a table. A note-taker recorded the order of speakers and initial words. The following question were used to guide discussion in the group:

1. How have you found these six months of study?

2. Have there been any drawbacks from having spirometry conducted by the nurse in your practice?
3. How have you used the spirometry results?
4. Were there any barriers? Were you able to make the best use of the spirometry results?
5. Are there any comments regarding spirometry, the study or alternative ways of using spirometry in general practice?

In order to stimulate discussion about use of spirometry in the diagnosis of COPD, scenarios were used in which two examples of spirometry results and flow-volume curves were provided to each participant. Some clinical information on the subject was provided, smoking history, MRC breathlessness grade, self-rating of own health, strength of belief that smoking has caused lung damage and strength of belief in the benefits of quitting smoking.

Discussion around the scenario was facilitated with the following questions:

6. Would you feel confident making a diagnosis from this spirometry result?
7. How would this result add to your ability to make a diagnosis?
8. What would you say to this patient about these results?

[Appendix 13: Spirometry examples]

4.11.1.10 Follow up spirometry result: records extraction

Participants with spirometry results in the following categories were selected for review of their practice records by the following criteria:

1. Classified by the algorithm as OLF or RLF
2. Classified by the algorithm as NLF and a current smoker.

Records were reviewed after a minimum period of three months post-spirometry to allow a reasonable opportunity to organise follow up with the GP and completion of any further investigations.

4.11.2 "Usual Care" model

4.11.2.1 Recruitment of individual participants

In the practices allocated to the "usual care" model, posters promoting spirometry in patient waiting areas or computer prompts to doctors for spirometry screening in the target group could be used, but doctors used their clinical discretion to carry out testing. The purpose of the posters was to increase general awareness but not to request volunteers. Participants were recruited when a GP performed spirometry on a

patient in the target group, or referred such a patient to the practice nurse for spirometry.

Any practice patient in the target group who had lung function measured was given an information sheet and a one-page questionnaire, based on that used in TN practices (omitting questions on the reasons for agreeing to or refusing spirometry, and self-rating of general health, lung damage and benefits to quitting smoking) [Appendix 14: Questionnaire A-UC].

Booklets published for Quit Tasmania on smoking cessation were supplied to each practice to be given to all current smokers.

Results of spirometry tests performed were downloaded for analysis at monthly intervals by researchers and a payment of $10 was made for each test on a patient in the target by whom a Questionnaire A-UC was completed. GPs also used the spirometer for clinical indications or medical examinations for patients of any age. The number of tests performed was assessed. Researchers assessed the quality of downloaded tests and classified results according to the study algorithm.

4.11.2.2 Consent

Each participant in the target group who had spirometry test in the practice was supplied with written information sheet. If the patient consented to involvement in the study they were asked to sign the consent form attached [Appendix 15]. A signed copy of the consent form and the information sheet was given to each participant. A signed consent form was retained for each participant.

4.11.2.3 Questionnaire A

This was completed after spirometry by each participant recruited in the target group [Appendix 14]. They were returned to practice staff and collected by researchers monthly or returned direct to the research office by mail (reply-paid envelope supplied).

4.11.2.4 Spirometry

An EasyOne spirometer was supplied to each practice with a supply of spirettes. Practice nurses and doctors who performed testing had received training in spirometry and use of the EasyOne spirometer. They recorded the participant's height and patient details in the spirometer. They were requested to continue testing

until three acceptable tests had been performed or until the patient declined to continue.

4.11.2.5 Assessment of spirometry quality

All spirometry tests were printed via a printer linked to a PC in the research office. Printed results were de-identified apart from the study identification number and retained for assessment of quality and comparison of classification by a respiratory physiologist.

4.11.2.6 Follow up spirometry result: records extraction

Participants who had given consent whose spirometry results were classified in the following categories, were selected for review of their practice records:

1. Classified by the algorithm as OLF or RLF
2. Classified by the algorithm as NLF and a current smoker.

Records were reviewed after a minimum period of three months post-spirometry to allow a reasonable opportunity to organize follow up with the GP and any further investigations to be completed.

4.11.2.7 Focus group follow up of spirometry model

A focus group lasting 90 minutes was scheduled with each participating practice after completion of the first six months. All GPs, practice nurses and practice managers were invited to attend. Groups met at the practices premises, normally outside consultation times. The facilitator greeted participants and refreshments were served while they gathered. The facilitator commenced with an overview of the study, an explanation of the conditions that applied to the discussion: confidentiality, anonymity, and the right to withdraw or not to answer a question. All participants were asked to sign and consent form and permission was sought to turn on a tape recorder. A recording was made using a multi-directional microphone situated centrally on a table. A note-taker recorded the order of speakers and initial words.

The following question were used to guide discussion in the group:

1. How have you used the spirometer?
2. Have there been any benefits from having the easy to use spirometer in your practice?
3. Have there been any drawbacks from having the spirometer in your practice?

4. Were there any barriers? Were you able to make the best use of the spirometer?
5. Are there any comments regarding spirometry, the study or alternative ways of using spirometry in general practice?

In order to stimulate discussion about use of spirometry in the diagnosis of COPD, scenarios were used in which two examples of spirometry results and flow-volume curves were provided to each participant. Some clinical information on the subject was provided: smoking history, MRC breathlessness grade, self-rating of own health, strength of belief that smoking has caused lung damage and strength of belief in the benefits of quitting smoking. Discussion around the scenario was facilitated with the following questions:

6. Would you feel confident making a diagnosis from this spirometry result?
7. How would this result add to your ability to make a diagnosis?
8. What would you say to this patient about these results?

[Appendix 13: Spirometry examples]

4.11.3 Feedback on spirometry to practices

At the conclusion of twelve months in January 2006 all practices received a letter of thanks for their participation, and a report on their spirometry utilisation and quality of the tests performed by the practice.

4.12 Data management

4.12.1 MS Excel database

The trained nurses used an MS Excel spreadsheet to record data for each participant who was given a unique study identification number. Questionnaire data were entered manually during spirometry sessions and on receipt of completed questionnaires or those administered by telephone interview. Data from calibration of spirometers were recorded in an Excel spreadsheet. I performed a cross check to verify all data for accuracy.

4.12.2 SPSS database

A database in SPSS was created and maintained for each six-month period of the study. Data were either exported from the Excel spreadsheets or entered manually. The database was used for exploring, cleaning and tabulating data.

4.12.3 Microsoft Word

Taped focus group discussions were transcribed using Microsoft word and exported in rich text format.

4.12.4 NVivo software

Transcriptions were imported with allocated headings and participant codes in rich text format and saved in a project created for the study. Other memos, and attribute tables were stored in the project as they were created during the process of analysis.

4.13 Statistical analysis

4.13.1Software: SPSS

Quantitative data analysis was performed using Statistical Package for Social Scientists (SPSS version 12.0.1). Data obtained from the questionnaires A, B, C and practice record extraction were in the form of dichotomous (nominal and ordinal) variables and continuous variables. Spirometry test and calibration data were in the form of continuous variables.

4.13.2 Presentation of data

The distribution of continuous variables was explored visually using stem and leaf plots. The Kolmogorov-Smirnov and Shapiro-Wilks tests of normality were applied. For continuous variables with a normal distribution, results are presented as mean and standard deviation (SD). Where variables are non-normally distributed, results are presented as median and interquartile range (IQR).

4.13.3 Statistical tests

Decisions on the methods of data analysis are discussed separately for each research question.

4.13.3.1 Comparison of dichotomous variables

The Chi squared test was used to compare dichotomous variables between groups and Fisher's exact test was used if any of the expected values in the comparison were less than five. Alpha level was set at 0.05 and p values of < 0.05 were taken as indicating significant differences.

4.13.3.1.1 For TN and UC practices variables compared were:

Gender, smoking status, current respiratory diagnosis, reported use of respiratory medications.

Number and quality grades of spirometry tests performed in target group participants

Classification of spirometry by study algorithm

Proportion of participants with OLF or RLF having data extraction

Recorded use of respiratory medications both before and after spirometry

New medication recorded

Medication change recorded

Recording of repeat spirometry, referral for respiratory specialist consultation, chest radiology and pulmonary rehabilitation.

Recording of respiratory symptoms, exacerbations and physical activity and smoking status

4.13.3.1.2 For NLF, OLF and RLF groups variables compared were:

Gender, smoking status, current respiratory diagnosis and medication use

Proportion of participants with FER <0.7

4.13.3.1.3 For TN practices variables compared were:

Number of participants agreeing to or declining spirometry

Gender and smoking status of participants agreeing to or declining spirometry

4.13.3.1.4 For those with AO (FER<0.7) variables compared were:

Gender, smoking status, current respiratory diagnosis, and current use of respiratory medications.

Severity of airflow limitation

4.13.3.1.5 For smokers in NLF and OLF groups variables compared were:

Gender, smoking history, current respiratory diagnosis, current use of respiratory medications, attaining education post grade 12, presence of dyspnoea on exertion, proportion living with a partner,

Making quit attempt > 24 hours within past 12 months

MRC functional dyspnoea grades

TTM stage pre-spirometry and post-spirometry

Proportion consulting GP following spirometry

Self-efficacy and social support for quitting

Smoking status at follow up

Quit attempts made during 3 months

Stage shifts- forwards, backwards, no change

4.13.3.1.6 For smokers who quit and continuing smokers variables compared were:

Gender

MRC functional dyspnoea grades

TTM stage

GP record of smoking status and smoking cessation advice

GP record of new respiratory diagnosis and medication

Banded scores for self-rated general health, lung damage and benefits of stopping smoking

4.13.3.2 Comparison of paired categorical outcomes

McNemar's non-parametric test for two related dichotomous variables was used to compare dichotomous nominal variables measured before and after spirometry.

4.13.3.2.1Variables compared were:

Use of respiratory medications pre- and post-spirometry

4.13.3.3 Continuous variables with normal distribution in two-group comparison

Two independent groups were compared using Student's T-test. Levene's test for equality of variances was applied and if homogeneity of variables was found, the unequal variance estimates of significance were used. The paired T-test was used to compare repeated measures of a variable. A result was considered significant where the *p* value <0.05 and 95% confidence intervals excluded zero.

4.13.3.3 1 For TN and UC practices variables compared were:

Age, smoking history

4.13.3.3 2 For participants with/without AO (FER<0.7) variables compared were:

Age, smoking history

4.13.3.3 3 For smokers in NLF and OLF groups variables compared were:

Heaviness of Smoking Index

4.13.3.3 4 For smokers who quit and continuing smokers variables compared were:

FEV1 % predicted

4.13.3.3 5 For spirometer calibration checks using a random compared to the dedicated spirette variables compared were:

Deviations from 3-litres for expiratory checks and inspiratory checks (paired test).

4.13.3.3 6 For spirometer calibration checks using a random or the dedicated spirette variables compared were:

Absolute expiratory and inspiratory volumes

Inspiratory and expiratory calibration test volumes

4.13.3.4 Continuous variables with normal distribution in three-group comparison

Means of variables for more than two groups were compared by a one-way analysis of variance (ANOVA) for variables that met the assumptions of population normality and homogeneity of variance.

4.13.3.4 1 For target group participants in NLF, OLF and RLF groups variables compared were:

Age

4.13.3.5 Continuous variables with non-normal distribution

The non-parametric Mann-Whitney test was used for comparisons between two independent groups when variables were not normally distributed.

4.13.3.5 1 For target group participants in TN and UC practices variables compared were:

FEV1 % predicted, pack years smoking,

Frequency of consultations pre-spirometry and post- spirometry

4.13.3.5 2 For participants with/without AO variables compared were:

Self-rated general health and lung damage

MRC functional dyspnoea grades

4.13.3.5 3 For smokers in NLF and OLF groups variables compared were:

Age, age of starting smoking, number of cigarettes smoked per day, pack years smoking, % predicted FEV1

Self-rated general health, lung damage and benefits of stopping smoking

4.13.3.5 4 For smokers who quit and continuing smokers variables compared were:

Age,

Pack years smoking, Heaviness of Smoking Index, Number of cigarettes/day

Self-rated general health, lung damage and benefits of stopping smoking

4.13.3.6 Paired continuous outcomes with non-normal distribution

The Wilcoxon signed rank test was used for comparison of repeated measures of variables that were not normally distributed and takes into account the magnitude of the differences between the two paired variables.

4.13.3.6.1 For record review in TN and UC practices variables compared were:

Number of consultations pre-and post-spirometry

4.13.3.7 Continuous variables with non-normal distribution in three-group comparison

The Kruskal-Wallis non-parametric test for comparison of more than two independent groups was used to compare differences for variables that violated the requirements of normality of distribution and homogeneity of variance required for ANOVA.

4.13.3.7.1 For target group participants in NLF, OLF and RLF groups variables compared were:

Pack years smoking

Self-rated general health and lung damage

FEV1 % predicted

MRC functional dyspnoea grades

4.13.3.7.2 For smokers in different stages of change at baseline variables compared were:

Self-rated general health, lung damage and benefits of quitting

4.13.3.8 Agreement on spirometry classification

Cohen's kappa was used for agreement between spirometry evaluation using the study algorithm by the trained nurse and a physiologist.

4.13.3.9 Agreement between two measures

The Bland-Altman plot is method of comparing the agreement between two measures of a clinical outcome (272). A plot of the difference between the measurements against their mean is displayed graphically. The limits of agreement are set by the requirement for measured calibration volumes not to differ by more than 3.5% from 3-litres (113).

4.13.3.9.1 For calibration checks with dedicated or random spirette variables compared were:

Measured and target inspiratory and expiratory calibration volumes by calibration flow and time in use

4.13.3.10 Correlation- non parametric procedure

Correlation between categorical variables with a skewed distribution was investigated using Spearman’s rank order test.

4.13.3.10.1 For smokers in the OLF and NLF spirometry feedback:

Self-rating for general health and FEV1% predicted
Self-rating for general health and lung damage
Self-rating for general health and quit benefit
Self-rating for general health and smoking exposure
Self-rating for lung damage and quit benefit
Self-rating for quit benefit and smoking exposure

4.13.3.10.2 For smokers who quit and continuing smokers:

Self-rating for general health, lung damage, benefits of smoking cessation and FEV1% predicted.

4.13.3.11 Logistic regression

Regression models are a category of statistical model that describe mathematically the dependence of one variable on one or more other variables (273). Logistic regression analysis is one type of multivariable modelling procedure that is used to assess the relationship between two or more continuous or categorical, explanatory (independent) variables and a single binary outcome variable such as mortality or morbidity (smoking or quit smoking) (274,275). In linear regression, the relationship between the predictor and response variables is described by the equation:

$$\hat{y} = \alpha + \beta x$$

where $\hat{y}$ represents the predicted value on the dependent variable, x represents an individual value on a predictor variable, α corresponds to the intercept of the regression line and β the slope of the regression line (coefficient).
The mathematical model for logistic regression is similar, but equations can be developed to predict probabilities for either of the dichotomous outcomes. The ratio of probabilities for the dichotomous outcomes is the odds ratio, obtained from the antilogarithm of the coefficient in the regression equation (276). The odds ratio represents a change in the estimated odds of the outcome compared to the reference group or when the continuous variable increases by one unit. Since odds ratios are an accepted measure of association in medical research, logistic regression analysis was used in this study to explore the effect of the independent variable of interest, spirometry feedback on sustained smoking cessation and making at least one quit attempt lasting more than 24-hours three months post-spirometry (275). Logistic regression analysis allows the flexibility to use continuous explanatory variables, that may not be normally distributed (e.g. self-rated beliefs about health) and dichotomous variables such as gender. Where necessary, continuous variables were transformed using bands into ordered categorical variables. Tests of linear trend were performed with ordered categorical variables using the category level as a covariate. Interactions, in which the impact of one variable depends on the level of another variable, were examined in the data and are reported where significant interactions were found (275). The percentage for the dependent variable that was correctly identified by a logistic regression model was assessed by reporting the value of Nagelkerke' R Square (277).

4.13.3.12 Multinomial logistic regression

Multinomial logistic regression is an extension of binary logistic regression when the categorical dependent outcome has more than two levels (278). This analysis computes separate equations for the comparison of outcome categories against a designated reference category. The outcome of interest according to the study hypothesis was stage shift in the Transtheoretical Model. There were three categories for this outcome: forward shift, no change or backward shift. No stage change was designated as reference category. The effects of the independent variable of interest, spirometry feedback, and other variables thought or known to influence smoking cessation, were investigated in univariate and multivariate analyses. Interactions between spirometry feedback and perceived health beliefs were examined.

4.14 Specific roles taken by candidate in investigations

Primary role in design and selection of methodology for preliminary study

Prepared outcome instrument measurement tools for preliminary study

Performed practice records data extraction in preliminary study (80%)

Data entry for quantitative outcomes in preliminary study

Preliminary study database manager

Primary analysis of preliminary study quantitative data

Conducted focus group in preliminary study

Analysed focus group and interview data in preliminary study

Primary role in design and selection of methodology for intervention study

Prepared submission for ethics approval

Wrote study information for participating GPs and patients

Designed, prepared and pilot tested questionnaires for intervention study

Recruited, conducted information and initiation visits to all practices in intervention study

Organised and participated in spirometry training in all practices

Verified data entry to Excel spreadsheet

Designed SPSS database and performed all data entry

Primary analysis of quantitative data in intervention study using SPSS

Consulted and acted upon advice from professional statisticians for final analyses

Organised and conducted all focus groups

Transcribed four focus group recordings

Read and analysed all focus group transcripts

Performed extraction of data from patient records in practices (75%)

Prepared summary of results for all practices and newsletter of the division of general practices

Acted as general coordinator and database manager of intervention study, maintained minutes and records of progress meetings.

Chapter Five

Stability of the EasyOne Spirometer

5.1 Rationale for calibration checks

The EasyOne™ spirometer was chosen for use in the study, on the basis of its ease of use, accuracy and stability (see Methods, Chapter 4.10.1.1). An accurate spirometer is fundamental for obtaining valid measurements for interpretation and diagnosis of respiratory disease. Although the manufacturer of the EasyOne claimed that the device remains accurate and therefore does not require daily assessment of its calibration, there was no published data to support this in a clinical setting. The accuracy and stability of the EasyOne spirometer was therefore assessed regularly during the period of use in primary care during the intervention study.

The relationship between sensor-determined values of flow or volume and the actual flow or volume is established by the manufacturers of a spirometry device using computer-generated waveforms (225). However, the user in the laboratory or clinic is responsible for ensuring that measurements made by a device remain accurate (113). This is achieved through a calibration check procedure to validate that a device is within specified accuracy limits. The required accuracy limits for a spirometry device are ± 3% (113). A volume calibration check is performed with a 3-L syringe that is required to have accuracy limits of ± 0.5% or ± 15ml (113). Calibration checks were undertaken during the intervention study comparing two models of spirometry delivery in primary care. An assessment of the accuracy of the spirometers used over a 12-month period are presented in the following sections. Subsequent chapters will present results of spirometry tests and the follow up of those tested.

5.2 Procedures

Six examples of the EasyOne spirometer were subject to regular calibration checks during a period up to 412 days. Two spirometers were used by trained nurses to perform opportunistic testing at regular spirometry sessions in practices. The calibration of these spirometers was checked weekly. The other four spirometers were each assigned to two general practices for six month periods, during which calibration checks were carried out monthly.

Calibration checks were carried out using a calibration syringe, with a certified accuracy of ±0.5%, to deliver 3.00 litres of room air through the spirometer (expiratory calibration check) then withdrawn back into the syringe (inspiratory calibration check). Two trained nurses performed the manoeuvres and were instructed to first empty then fill the syringe within 6 seconds. From commencement of the study in November 2004, calibration checks were performed regularly using the same mouthpiece (spirette^{TM}). From April 2005 paired syringe calibrations were conducted, using both the single dedicated spirette reserved for calibration and also a new spirette that was randomly selected on each occasion. It was felt this would provide information relevant to the actual clinical setting that would occur in practice where some practices may reserve a spirette for calibration only (dedicated) whilst others may use a new spirette (random) on each occasion.

5.3 Analysis

For each device, the mean and standard deviation of expiratory and inspiratory volumes (L) and flows (L/sec) were calculated for measurements obtained using dedicated and random spirettes. Differences between measured and 3.00 L target volume were plotted against length of spirometer use and against flow. To meet the accuracy requirement the volume recorded by the spirometer using the 3-litre syringe should be within the range ±3.5% (i.e. 2.895-3.105L). Paired calibrations with dedicated and new spirettes were compared using the method of Bland and Altman (272).

5.4 Results

5.4.1 Frequency of spirometer use

The six EasyOne spirometers were used in clinical practice for 54 weeks. Throughout the study, each spirometer functioned reliably with no obvious hardware or software problems. As detailed in Table 5.1, the six spirometers were used to perform a total of 1,224 spirometry tests. During the study a total of 149 syringe calibration checks were performed on the six spirometers, of which 92 were paired checks.

5.4.2 Calibration checks

5.4.2.1 Single calibration checks

During the first 165 days of spirometry testing, 467 tests were performed and all expiratory and inspiratory calibration checks (n=57) during this period carried out on each of the six spirometers using the dedicated spirette alone met the international accuracy criterion of 3.00±0.105 L (113,225) (See methods, Chapter 4.10.4). Results are shown in Table 5.2. Calibration checks were performed over a wide range of flows, ranging from 1.27 L/sec to 7.52 L/sec for expiratory flow and from 0.81-8.34 L/sec for inspiratory flow. Deviation from the expected volume did not exceed 90mls for expiration or 80mls for inspiration on any occasion. The mean volumes obtained during calibration were 3.026 L (SD 0.034) for expiration and 2.983 L (SD 0.035) for inspiration.

Table 5.1: Usage data for each spirometer during twelve months

Spirometer #	*Spirometry tests*	*Calibrations*	
		Dedicated	Random
47996	39	16	9
50758	3	15	9
50759	65	10	6
50763	426	51	30
50764	60	10	5
50946	631	47	33
Total	1224	149	92

Table 5.2: Results of single calibration checks on six EasyOne spirometers using a dedicated spirette

		Dedicated spirette (n=57)			
		Measured		Deviation from 3.00L	
		Flow (L/s)†	Volume‡ (L)	Absolute (L)	%
Expiration	Mean	4.848	3.026	0.026	0.869
	Range	1.27-7.52	2.95-3.09	-0.05-0.09	-1.67-3.0
	95%CI	2.36-7.34	2.96-3.09	-0.04-0.92	-1.34-3.08
	SD	1.269	0.034	0.034	1.126
Inspiration	Mean	4.867	2.983	-0.017	-0.560
	Range	0.81-8.34	2.92-3.05	-0.08-0.05	-2.67-1.67
	95%CI	1.82-8.44	2.91-3.05	-0.09-0.05	-2.87-1.75
	SD	1.823	0.035	0.035	1.177

(†Mean flow generated during calibration. ‡ Volume recorded by spirometer during procedure)

5.4.2.2 Paired calibration checks

The stability of the EasyOne spirometer accuracy was confirmed by the results of 23 weeks of paired calibration checks.

There were 92 paired expiratory and inspiratory calibration checks performed on six spirometers over 249 days whose results are shown in Table 5.3. All expiratory and inspiratory calibration checks performed on each of the six spirometers using either the dedicated or a random spirette met international accuracy criteria of 3.00±0.105 L (113).

Although all calibrations met the accuracy criteria, the mean volume recorded by the spirometers for both the expiratory and inspiratory checks was significantly ($p<0.001$) higher when using random compared with a dedicated spirette (Table 5.3). Similarly, there was a significant difference ($p<0.001$) between inspiratory and expiratory calibration test volumes, with expiratory volumes higher than inspiratory, whether the measurement was made using the dedicated or a random spirette.

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Table 5.3: Results of calibration checks on six EasyOne spirometers during paired checks using the dedicated spirettte or a randomly selected spirette.

	Dedicated Spirette				*Random Spirette*			
	Flow[†] (L/s)	Measured Volume[‡] (L)	Deviation from 3.00L		Flow[†] (L/s)	Measured Volume[‡] (L)	Deviation from 3.00L	
			Absolute (L)	(%)			Absolute (L)	(%)
Expiration								
Mean	5.828	3.012	0.012	0.384	6.183	3.045	0.045	1.522
Range	2.37-8.83	2.94-3.09	-0.06-0.09	-2.00-3.00	2.87-8.51	2.91-3.10	-0.09-0.10	-3.00-3.33
95%CI	3.41-8.83	2.95-3.08	-0.05-0.08	-1.80-2.54	3.81-8.55	2.98-3.11	-0.02-0.11	-0.76-3.81
SD	1.234	0.033	0.033	1.097	1.209	0.035	0.035	1.163
Inspiration								
Mean	5.531	2.963	-0.037	-1.228	5.590	3.003	0.003	0.107
Range	1.08-9.28	2.91-3.04	-0.09-0.04	-3.00-1.33	2.22-8.40	2.92-3.07	-0.08-0.07	-2.67-2.95
95%CI	2.58-8349	2.95-3.08	-0.09-0.02	-3.08-0.62	2.94-8.24	2.93-3.08	-0.07-0.08	-2.33-2.54
SD	1.504	0.028	0.028	0.944	1.351	0.037	0.037	1.242

([†]Mean flow generated during calibration. [‡] Volume recorded by spirometer during procedure)

5.4.3 Stability of calibration checks with time

Volume accuracy for all spirometers using the dedicated spirette remained stable for 412 days with no evidence of deterioration over time (Figure 5.1). The absolute difference between measured and target volume (3.00L) is shown for all six spirometers as a function of time. When a randomly selected spirette was used, accurate measurements were obtained using all six spirometers over 249 days (Figure 5.1).

5.4.4 Stability of calibration checks with airflow

The difference between the measured and target volume (3.00L) and the mean flow generated during the calibration procedure varied across a range from 1.08-9.28 L/sec using either the dedicated or a random spirette is shown in Figure 5.2. No association was found between the deviation from target volume and the mean flow.

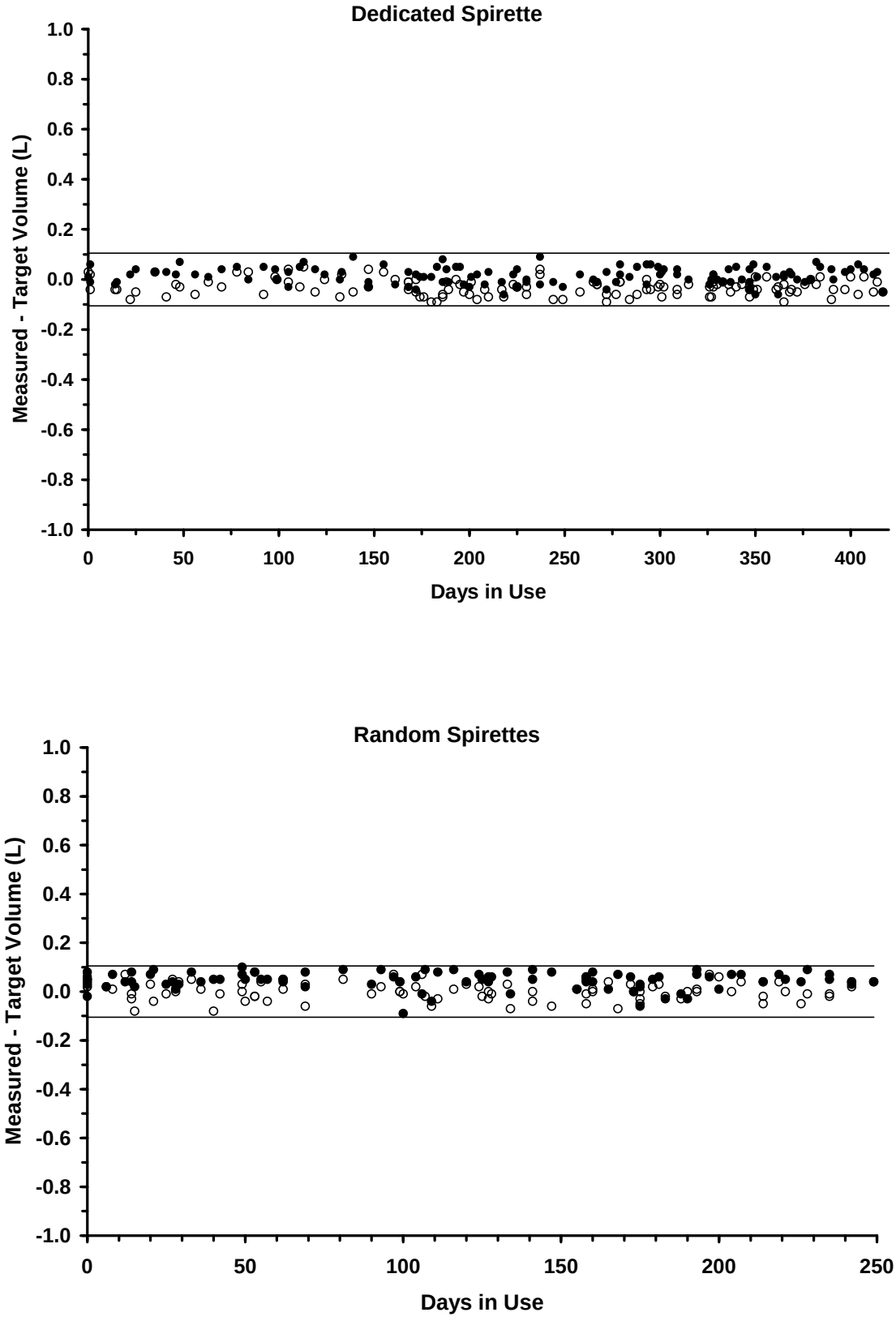


Figure 5.1: Accuracy of the expiratory (solid circles) and inspiratory (open circles) calibration checks for all six spirometers using a 3-L syringe.
[The lines show the upper and lower American Thoracic Society and European Respiratory Society accuracy limits (2.895 and 3.105L) when delivering 3.00L.]

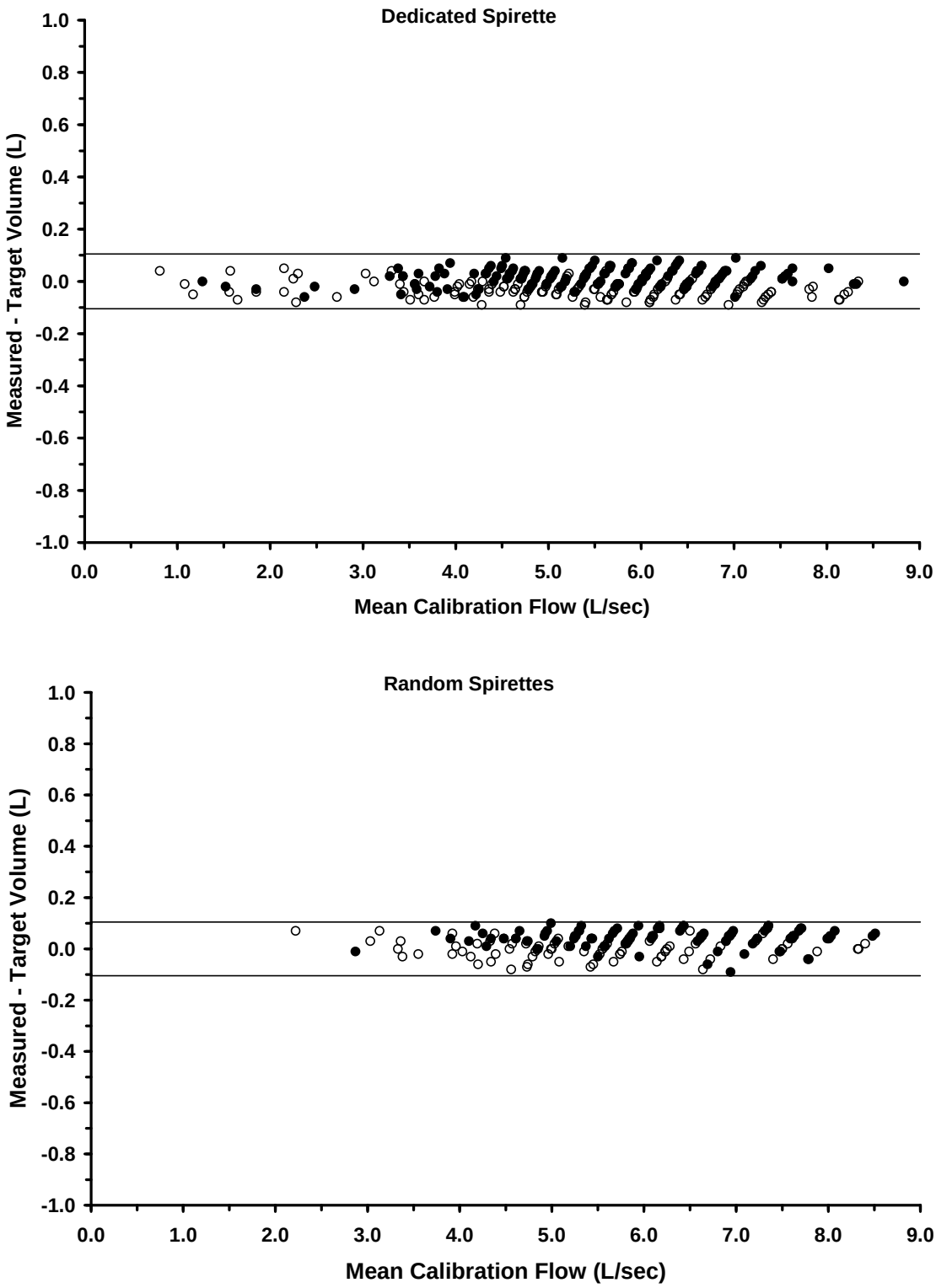


Figure 5.2: Accuracy of the expiratory (solid circles) and inspiratory (open circles) calibration checks using a 3-L syringe for all six spirometers as a function of the mean flow generated during the calibration.

[The lines show the upper and lower American Thoracic Society and European Respiratory Society accuracy limits (2.895 and 3.105L) when delivering 3.00L.]

5.5 Discussion

The results in this thesis provide strong evidence to support the claim made by the manufacturer that the EasyOne spirometer is accurate and maintains its accuracy during clinical use, for at least 412 days. This has practical implications in general practice, as it implies that this spirometer does not require daily calibration as recommended in the latest spirometry guidelines (113). However it is also recommended (279) that overall performance is checked weekly using a healthy non-smoking individual as a biological control (280,281).

Although this study has confirmed the stablility of the volume accuracy of the EasyOne spirometer, study procedures allowed investigation of other potential sources of variation in measurements. In additional checks performed using a new spirette selected randomly on each occasion, small differences were found between the syringe calibrations that used different spirettes. These differences are probably related to minor variations in the cross-sectional area of spirettes. The result for volume is obtained by the spirometer through integrating the flow signal with respect to time. Flow is derived by dividing the measured gas velocity by the internal cross-sectional area of the spirette. However, as variability between calibrations was similar for the one dedicated and randomly selected spirettes, this indicates that the manufacturing tolerances with respect to variations in internal cross-sectional area were very small.

The small difference in expiratory and inspiratory volume seen in calibration checks, with expiratory volumes being consistently greater, may be due to the operator handling the syringe. This would result in a slight increase in temperature and thus a small increase in volumes measured during the expiratory manoeuvre.

The EasyOne spirometer, costing about $3,250 in Australia (106), is accurate compared to standard office-based spirometers (282,283) (284). In one study on children with asthma comparing the EasyOne and a dry rolling seal spirometer simultaneously, reproducibility across devices was 97% for FEV1 but only 75% for FVC (283). An “in-field” study in a community fair found good agreement between the EasyOne and a laboratory spirometer for FEV1 and FEV6 (284).

Performing spirometry in primary care is generally accepted as justified in terms of test validity as long as there is adequate operator training (285) but this acceptance is invalid if spirometer calibration is inaccurate. Surveys in 2004 in Australia (101) and the US (114) confirmed that in practices owning a spirometer, daily calibration

checks were not routinely carried out. Although it has been suggested that implementation of quality assurance checks for the equipment, as well as for the test procedure itself, ought to be inevitable in primary care if spirometry is used in the management of patients (285) it seems unlikely that GPs will change their practice and implement daily accuracy checks. Thus, an alternative solution is required to the daily use of 3-L calibration syringes to check the accuracy of spirometers intended for use in primary care, as suggested by the National Lung Health Education Program in the US (5). Intuitively, the availability of reliable, stable spirometers that do not require daily calibration checks would provide such a solution and ensure quality spirometry by reducing instrument-related measurement errors that, if present, would always result in poor quality spirometry (286).

Features of the EasyOne such as provision of feedback to the operator on the quality of each test, the ability to store the three best tests (or values) for up to 700 tests and low risk of cross infection are advantages in addition to stability of calibration, that make it suitable for use in primary care to provide good quality spirometry. The same advantages formed the basis of its selection for the field-based international COPD prevalence study (64).

Spirometry is now recommended in clinical guidelines for COPD (15,54,287) and asthma (288) and thus there should be increasing use of spirometry in primary care as or when these recommendations are incorporated into practice.

Information on comparative features of spirometers is available to practices in Australia in a Spirometer Buyers guide (106). The stability of calibration is an important criterion in the selection of a spirometer. Of the spirometer models listed in the guide, 22 specify that a daily calibration check is recommended and 7 do not recommend a daily check, but probably should. While the manufacturer of five models using a different technology for measurement states that calibration is not required, the manufacturer of the EasyOne claims that as the ultrasonic flow measurement is independent of gas composition, pressure, temperature and humidity, errors due to these variables are eliminated. This is the justification for stating that daily calibration checks are unnecessary.

However, manufacturers' claims require substantiation in the field (285). My study confirms the stability of the EasyOne over one year when used in primary care. It is supported by confirmatory evidence of stability found in a study using 70 spirometers for up to six months (289).

Thus, current spirometer guidelines (113) stating the need for daily calibration may need to be revised in the light of these findings, at least for the latest generation of spirometers using new technology, such as ultrasound in the EasyOne.

Chapter Six

A comparison of models for spirometry provision in primary care for patients at risk of COPD

6.1 Recruitment of subjects

Recruitment of participants in practices commenced in November 2004, at the earliest practical date following the practice set-up visit and after the practice-based training course in spirometry (Table 6.1). Recruitment continued for twenty-six weeks in each practice, allowing for non-attendance by the trained nurse during vacation periods. Recruitment commencement dates for each practice are shown in Table 6.1.

Table 6.1: Study commencement dates for recruitment of participants

Practice	*Period TN*	*Period UC*
Practice 1	2 November 2004	14 May 2005
Practice 2	8 June 2005	1 November 2004
Practice 3	4 November 2004	14 May 2005
Practice 4	3 June 2005	1 November 2004
Practice 5	1 November 2004	14 May 2005
Practice 6	2 June 2005	1 November 2004
Practice 7	3 June 2005	1 November 2004
Practice 8	2 November 2004	14 May 2005

6.1.1 TN practices

The intended sequence for opportunistic recruitment of participants in the target group in TN practices relied on a receptionist offering study information to patients as they arrived in the practice, if they were over 35 years of age and had ever smoked regularly (Chapter 4.11.1). However, in the first period it became apparent within a few weeks that receptionists in some practices were too busy and did not have time, forgot to do so or were unwilling to do so. To achieve full opportunistic recruitment, the visiting nurses also directly invited patients in the waiting room to participate. This practice continued in all practices during the TN period for the remainder of the study. The visiting nurses also collected data on patients attending practices during

sessions; the total number booked, the numbers of those who had never smoked, those under 35 years of age or those who had been asked previously.

Table 6.2 shows data on the number of GPs consulting, the number of patients attending at the surgery and the number participating in testing during spirometry sessions for each practice. Numbers of target group participants that had spirometry, varied among the eight practices from 14 to 194 (median 161) in TN period 1 practices and 85 to 122 (median 109) in TN period 2 practices. The median number of tests per session was 3 in practices 1-6 and 2 in practice 7.

Recruitment in practice 8 was far lower than in the other seven practices during the TN intervention period. In total only 14 participants had spirometry, with 62% of nurse sessions not resulting in recruitment of any participants. This practice had around 5,000 active patients and five part-time GPs. It was not possible to obtain full details of patients attending, owing to limitations of software used in this practice. From the observations of the visiting nurse and counts carried out by receptionists during spirometry sessions, it was apparent that there were fewer current smokers and a higher proportion of patients attending aged under 35 years (65% on one day). In other practices, the mean proportion of patients declaring themselves to be life long non-smokers ranged from 13.5% in practice 2 to 33.6% in practice 4 and the median proportion of patients under 35 years old ranged from 21% in practice 1 to 33% in practice 6.

Total target group spirometry test numbers were higher during period 1 than period 2, 549 compared to 427. This difference is not unexpected, as spirometry had been performed previously during the UC intervention period on patients in the target group, thus reducing the pool of potential participants in period 2.

TN intervention	*P 1*	*P 2*	*P 3*	*P 4*	*P5*	*P 6*	*P 7*	*P8*
Period order	1	2	1	2	1	2	2	1
TG spirometry tests	199	123	188	114	148	85	105	14
TG tests/week†	7.7	4.7	7.2	4.4	5.7	3.3	4.0	0.5
GPs consulting / session *	4 (2-5)	5 (3-5)	4 (3-5)	2 (1-2)	2 (1-2)	2 (1-2)	2 (1-3)	2 (2-3)
Patients booked / session *	43 (23-51)	30 (15-40)	38 (26-55)	15 (6-25)	21 (7-28)	21 (10-25)	14 (7-27)	21 (20-30)
% patients aged <35 years *	21 (15-52)	37 (20-52)	24 (12-43)	28 (15-75)	22 (9-33)	38 (14-60)	33 (11-75)	65 (range N/A)
% patients never-smoker/ session †	22.2	13.5	19.6	33.6	22.6	15.6	15.6	N/A
Spirometry tests / session *	3 (1-6)	3 (0-5)	3 (1-8)	3 (0-7)	3 (1-6)	3 (1-6)	2 (0-5)	0 (0-1)
Refuse spirometry / session *	5 (1-10)	3 (0-9)	3 (0-6)	1 (1-6)	2 (1-5)	1 (0-4)	1 (0-10)	N/A
% sessions no spirometry †	8.3	2	4.3	14.3	2.1	8	4.3	62

Table 6.2: Recruitment of participants in practices during TN period.

(TG=target group, Data presented as: *median & range; † mean. Practices paired for randomisation shown in adjacent columns, second period TN practices shaded)

6.1.2 UC practices

The number of participants recruited during the UC period in practices varied widely (Table 6.3). For practices in which the UC model was delivered first, recruitment ranged from 0-38 participants in the target group, although not all completed the full protocol (69/87 completed questionnaire A). Some practices used additional opportunities to recruit subjects in the target group for spirometry. Practice 2 prompted GPs with computer-generated on-screen reminders to offer a spirometry test with the practice nurse whenever a patient over 35 years known to be a smoker was seen. This practice had previously found using posters to advertise screening services was not effective. However, Practice 4 chose to display posters in the waiting room, advertising the opportunity for spirometry with their practice nurse to patients in the target group.

For practices in which the UC period occurred after the TN period, recruitment into the study was lower than anticipated, because many potential participants had already been recruited during the TN intervention period. Practice 1 performed many occupational medical examinations that included spirometry and tested 71 subjects in the target group and 187 subjects outside the target group. Most of these subjects were not regular patients at the practice.

Table 6.3: Recruitment of participants by practices in UC period

UC period	*P 1*	*P 2*	*P 3*	*P 4*	*P 5*	*P 6*	*P 7*	*P 8*
Order	2	1	2	1	2	1	1	2
Spirometry tests (target group + questionnaire A)	0	31	0	24	4	13	0	1
Spirometry tests (target group, no questionnaire A)	71	7	0	7	4	5	0	0
Spirometry tests (non-target group)	187	12	0	8	7	42	2	0
All spirometry tests/week†	9.9	1.9	0	1.5	0.6	2.3	0.1	<0.1
Target group tests/week	2.7	1.5	0	1.2	0.3	0.7	0	<0.1

(Data presented as: † mean. Practices paired for randomisation shown in adjacent columns, second period TN practices shaded)

6.2 Comparison of spirometry performed in TN practices and UC practices in the first six months

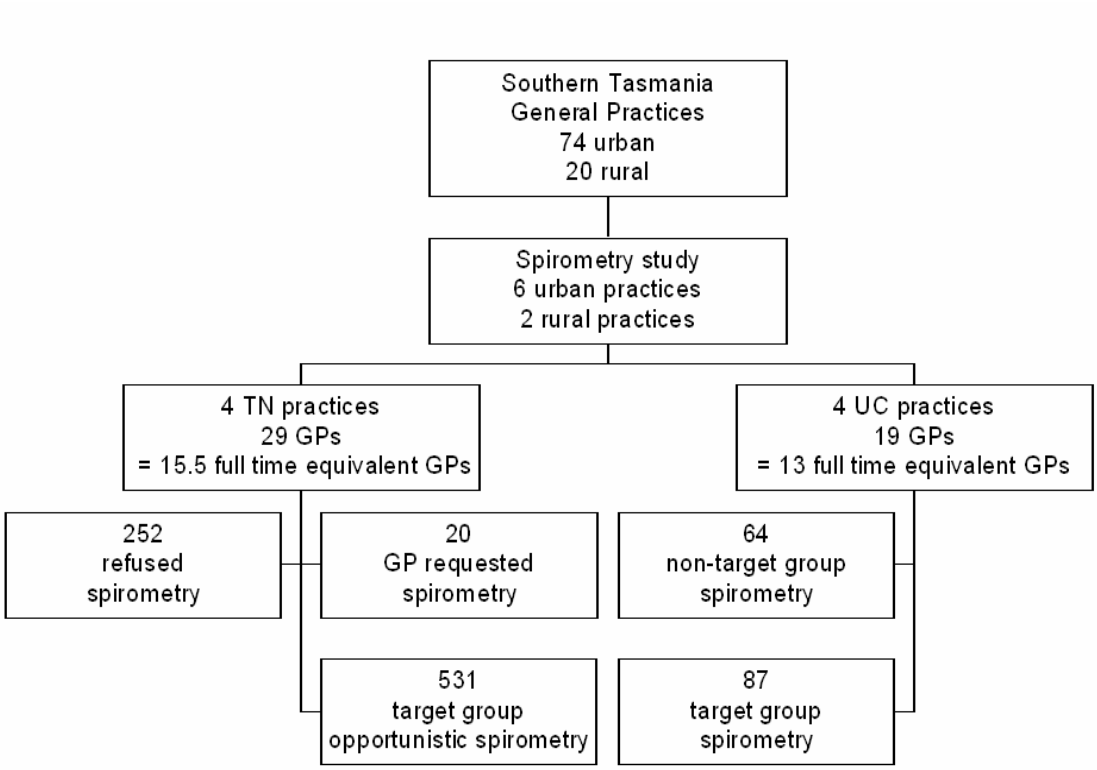
The effect of the order of intervention on recruitment in the second period had been anticipated during the design of the intervention study and an a priori decision had been made to compare outcome data on the models of spirometry in practices using the first period intervention data only.

6.2.1 Recruitment

Total study recruitment in the first six-month period was 956 participants in eight practices. TN practices recruited 805 participants of whom 531 participants in the target group had spirometry and 252 participants declined spirometry. UC practices recruited 151 participants, of whom 87 participants were in the target group (Figure 5.1). Both study arms recruited fewer participants for spirometry than had been anticipated in sample size calculations during the study design. In TN practices it was assumed nurses would each recruit 30 participants per week. The actual

recruitment was 805, an average of 15.5 participants per week, with 10.2 spirometry tests being performed on participants in the target group per week. The poor level of recruiting in practice 8 was responsible for loss of around 25% from the anticipated level. In addition, pre-study estimates had not taken into account differences in practice sizes and population. If all practices had recruited at the level of the highest recruiting practice, the study would have recruited around 70% of the pre-study estimate.

Figure 6.1: Flow chart for participant recruitment in first six-month period



6.*2.2 Comparison of number of spirometry tests in the target group in the TN and UC models*

In a comparison of the absolute number of spirometry tests carried out on participants in the target group, TN intervention practices tested over six times more patients than UC practices, performing 531 opportunistic tests compared to 87 tests.

6.2.3. Proportions of the target group undergoing spirometry in TN and UC models

In order to calculate the number of potential participants eligible for spirometry in each arm of the study, estimates of the eligible population comprising the denominator were made in TN and UC models using the following methods.

6.2.3.1 Proportion of target group undergoing spirometry TN model practices

In TN practices, the total eligible population (N_{TN}) consisted of all patients aged 35 or older who had ever smoked and who were attending the practices for any reason during opportunistic spirometry sessions. It was assumed that all potential participants would have the opportunity to participate, however early experience in some practices indicated that not all patients in the target group received an invitation from the receptionists, thereby invalidating this assumption. Recruitment procedures were changed where necessary to ensure an invitation was offered to every patient in the target group who attended. Trained nurses and receptionists asked all patients in the waiting rooms. Data on patients attending were collected. The number of people booked to attend during opportunistic spirometry sessions (N_b) could be divided into the numbers in categories: agreeing to spirometry (n_s), refusing (n_r), life long non-smokers (n_n), under 35 years old (n_y) plus the number previously asked (n_p) and missed an invitation to participate (n_m).

$$N_b = n_s + n_r + n_n + n_y + n_p + n_m$$

Data collected during spirometry sessions were used to calculate the proportions of people in the five categories. The proportion unaccounted for were assumed to have missed an invitation. The mean proportions are shown in Table 6.4. The calculation of potential participants who missed an invitation to participate could not be performed for practice 8, as data were lacking. As discussed in section 6.1.1, the demographic profile of patients attending practice 8 differed from the other practices. Fewer patients were in the target group and only limited data were obtained on

patients during spirometry sessions, therefore the average proportion from the other practices was used.
The number of patients in the target group who missed an invitation to participate (N_m) during six months was calculated as:

$N_m = (N_s + N_r)$ x % missed/100

The size of the overall target population in each practice was calculated as the sum of patients having spirometry (N_s), patients refusing spirometry (N_r) and patients in the target group who missed an invitation to participate (N_m) during six months:

$N_{TN} = N_s + N_r + N_m$

The calculations of N_{TN} and the proportion of the eligible total that underwent spirometry (P_{TN}) were performed for each practice and four practices overall (Table 6.5).
Overall 58.7% of the eligible target group underwent spirometry in TN practices.
The average practice proportion of the eligible target group that underwent spirometry in the four practices was 64.4% (13.8).
In addition to opportunistic recruitment during sessions, spirometry was advertised in practices using posters and this strategy was responsible for recruiting 13 participants. A doctor or other health professional, requested spirometry for eight participants.
Sensitivity analysis was performed in which participants recruited by advertising and referral were excluded. The number of target group participants who had opportunistic spirometry (N_{sos}) in TN practices during six months was:

N_{sos} = 531-8-13= 510
N_{TN} = 904

On this basis the proportion of the eligible target group that underwent opportunistic spirometry (POS_{TN}) was:

POS_{TN} = 510/904 = 56.4%.

Table 6.4: Percentages of patients attending practices during spirometry sessions in six months by categories: under 35 years old, life-long non-smoker, previously asked, agree to spirometry, refuse spirometry and missed invitation. (NK=not known)

	Proportions of all attending patients:					
Practice	*< 35 years*	*Never smoked*	*Asked before*	*Accept*	*Refuse*	*Missed*
1	23.8	22.2	14.3	7.2	10.7	21.8
3	26.5	19.6	29.3	8.9	5.5	10.2
5	21.5	22.6	19.5	15.1	9.4	12.7
8	65.0	NK	NK	NK	NK	18.0

Table 6.5: Number of patients in the target group participating in the study in TN practices in six months and percentage undergoing spirometry.

Participants	*Practice*				
	1	*3*	*5*	*8*	*Total*
Spirometry test (N_s)	193	179	145	14	531
Refused test (N_r)	104	113	34	1	252
Total $N_s + N_r$	297	292	179	15	783
Missed invitation (N_m)	65	30	23	2	110
Target group total (N_{TN})	362	323	202	17	904
Percentage tested (P_{TN})	53.3	55.4	71.8	82.4	58.7

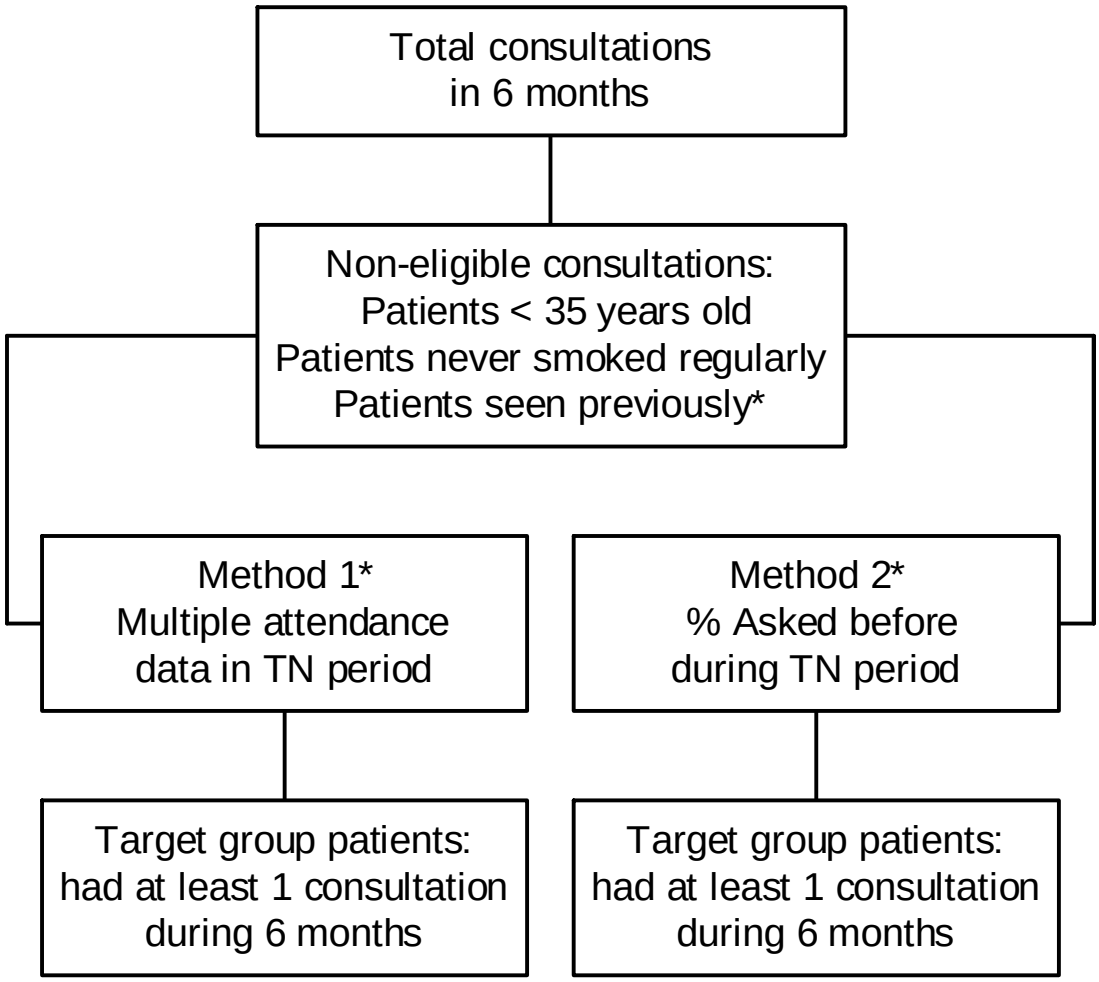
6.2.3.2 Proportion of target group undergoing spirometry in UC practices

In UC practices all patients aged 35 or older who had ever smoked were eligible for spirometry if they consulted a GP at least once during the six-month study period (N_{UC}).

This data was not collected during the study in UC practices nor was it feasible to obtain it retrospectively from practices through a search of practice computer records. Reliance on practice records alone would probably have yielded an underestimate as these are known to be substantially incomplete for data such as patients' smoking status.

Two methods were used to arrive at an estimate of the total number of target group patients who had at least one consultation during the six-month study period. This involved removing from the total number of consultations occurring during this period, those for whom it was a second or subsequent consultation. Two methods of calculating the number of repeat consultations were used and compared. Both methods used data collected on the demographic profile of patients attending the practices during six months when a trained nurse was visiting.

Figure 6.2: Methods used to estimate the eligible number of target group patients with at least one consultation in a practice during six months



6.2.3.2.1 Total number of consultations in six months

The total number of consultations (C_{total}) during the six-month study period was obtained from data collected by nurses in sessions during the second period (Table 6.2). This estimate is likely to be robust as there were no changes in GP numbers in practices between periods and no reason for there to be any significant difference in illness frequency between periods. Each study period included around 50% summer months and 50% winter months.

An estimate for C_{total} was obtained from practice consultation numbers during half-day sessions multiplied by the number of study weeks (26) and number of half-day sessions per week (10). The number of consultations for target group patients (C_{TGC}) was obtained from C_{total} using practice data on the proportions of patients consulting who were under 35 years or had never smoked shown in Table 6.2. Results are shown in Table 6.7.

6.2.3.2.2 Method 1 to estimate number of repeat consultations by using practice records data on repeat attendance

Data on repeat attendance were collected by extraction from the records in six practices for 264 participants in the target group, selected for follow up either because their spirometry result showed an abnormality (OLF or RLF) or they were currently smoking with normal lung function (NLF smoker).

Overall 43.1% of target group participants who underwent spirometry had data extracted from practice records on follow up. The number of consultations during the three-month periods prior to and following spirometry was obtained.

As the number of participants for whom data were extracted varied by practice with some practices having very small samples, the data were combined and an estimate obtained for the number of participants having multiple consultations during six months (Table 6.6).

Data from Medicare and Department of Veterans Affairs in 2001 (92) indicated that 50.9% of consultations were for patients aged over 45. In the study target group sample, the ages of study participants was normally distributed (mean age 52.9) with only 160 (18%) participants in the age group 35-45 years. The proportion of consultations for a patient in this age group is 3.6% for males and 15.4% for females (92). Attendance data at practices were weighted to allow 10% more single consultations in the overall practice population to allow for the higher proportion of older subjects on whom consultation frequencies were based. Australian data on

general practice activity in 2000-2001 indicates that patients in the age groups covering our target group population for whom data were extracted consult a GP more frequently than younger patients, with current and ex-smokers consulting more frequently than never smokers (92). Data on patients attending TN practices for any reason during spirometry sessions showed the median proportion of lifetime non-smokers was 20%. Attendance data were therefore weighted to allow for 20% more single consultations in never smokers.
FM is a factor representing the number of individual patients having one or more consultations calculated from data in Table 5.6.

FM= (20.57 + 2 x 6.84 + 3 x 13.03 + 4 x 13.52 + 5 x 10.50 + 6 x 10.92 + 7 x 5.7 + 8 x 5.02 + 9 x 5.27 + 10 x 10) / (1 + 2 + 3 + 4 + 5 + 6 + 7 + 8 + 9 + 10) = 8.6

The number of patients in the target group seen in six months (N_{UC}) was determined from all consultations (C_{CTG}) that occurred during the period using the formula:

$$N_{UC} = C_{CTG} / FM$$

Total consultation numbers (C_{total}), target group consultation numbers (C_{TGC}) and the number of target group participants who consulted at least once (N_{UC}) are shown in Table 6.7. Using the number of target group spirometry tests in the individual practices during six months, the proportions of patients tested in UC practices were calculated (P_{UC}).

6.2.3.2.3 Method 2 to estimate number of repeat consultations by using the proportion of patients who had been asked previously during TN spirometry sessions

Trained nurses recorded the number of patients attending during TN sessions in the second study period who had been previously asked to have spirometry. This was used as a crude measure of repeat consultation frequency. The total number of target group consultations was reduced by the mean percentage of “previously asked” patients recorded during the TN intervention to obtain the number of patients in the target group who had at least one consultation during 6 months (N_{UC}). As in method 1, using the number of target group spirometry tests in the individual practices during

six months, the proportions of patients tested in UC practices were calculated (P_{UC}). Results are shown in Table 6.8

6.2.3.2.4 Difference in results between methods for calculating the eligible population in UC practices

The proportions of target group participants who consulted at least once and underwent spirometry (P_{UC}) in the individual practices during six months in UC practices obtained by method 2 are considerable smaller than those obtained in method 1. The proportions obtained using method 1 range from 18.2% in practice 2 (on-screen reminders to GPs used) to 0% in practice 7, pooled estimate 7.7%. The range of proportions obtained by method 2 was 0 – 2.6%, pooled estimate 1.09%. Both estimates are low, though it is likely that method 2 underestimates the proportion of actual repeat attendances for consultations during six months and therefore over estimates the eligible number of target group patients with one or more consultation during the study period. The estimate from method 1 was considered more reliable and was used in the comparison with TN practices.

Table 6.6: Number and % of target group participants with 1 to >10 consultations during six months for practices 1-6 from practice records extraction used to estimate the population eligible for spirometry in Method 1

	Number of consultations in 6 months									
Practice	1	2	3	4	5	6	7	8	9	>10
1	9	6	6	9	8	7	4	5	5	12
%	13.0	8.5	8.5	12.7	11.3	9.9	5.6	7.0	7.0	17
2	1	2	4	3	1	2	2	1	2	3
%	5.0	9.5	19.0	14.3	4.8	9.5	9.5	4.8	9.5	14
3	6	4	9	11	18	9	9	8	7	17
%	6.0	4.1	9.2	11.2	18.4	9.2	9.2	8.2	7.1	17
4	3	1	3	2	1	0	1	1	0	1
%	23.0	7.7	23.1	15.4	7.7	0.0	7.7	7.7	0.0	8
5	8	7	4	9	5	6	2	2	5	6
%	15.0	13.0	7.4	16.7	9.3	11.1	3.7	3.7	9.3	11
6	0	0	1	1	1	2	0	0	0	2
%	0	0.0	14.3	14.3	14.3	28.6	0.0	0.0	0.0	29
1-6	27	20	27	35	34	26	18	17	19	41
%	16.2	7.1	13.6	14.1	10.9	11.4	6.0	5.2	5.5	10.0
Wt %	20.6	6.8	13.0	13.5	10.5	10.9	5.7	5.0	5.5	10.0

(% = percentage of patients with specified number of consultations in six months
Wt % = % weighted by 20% more single consultations)

Table 6.7: Participation for the target group in spirometry testing in UC practices in six months calculated using multiple attendance data from practice records.

Method 1	*Practices*				
	2	4	6	7	*Total*
Consultations/session	30	15	21	14	80
(% Patients <35 years)	(37)	(28)	(38)	(33)	
(% Patients never smoked)	(13.5)	(33.6)	(15.6)	(15.6)	
Consultations in 6 months (C_{total})	7800	3900	5460	3640	20,800
Consultations in target group (C_{TGC})	3861	1459	2533	1871	9,724
Target group patients seen ≥1 (N_{UC})	449	170	294	217	1130
Spirometry tests in target group	38	31	18	0	87
Percentage tested (P_{UC})	8.5	18.2	6.1	0	7.7

Table 6.8 Participation for the target group in spirometry testing in UC practices in six months calculated using proportion of patients being invited on more than one occasion to participate.

Method 2	*Practices*				*Total*
	2	4	6	7	
Consultations/session	30	15	21	14	80
(% Patients <35 years)	(37)	(28)	(38)	(33)	
(% Patients never smoked)	(13.5)	(33.6)	(15.6)	(15.6)	
Consultations in 6 months (C_{total})	7800	3900	5460	3640	20,800
Consultations in target group (C_{TGC})	3861	1459	2533	1871	9,724
(Mean % asked previously)	(10.6)	(18.3)	(8.8)	(34.4)	(17.9)
Target group patients seen ≥1 (N_{UC})	3452	1192	2310	1227	7,983
Spirometry tests in target group	38	31	18	0	87
Percentage tested (P_{UC})	1.1	2.6	0.8	0	1.09

6.2.4 Comparison of proportions of the target group undergoing spirometry in TN and UC models of delivery

6.2.4.1 Comparison of eligible proportions in TN and UC models of spirometry delivery

The proportions of the eligible population that underwent spirometry testing during six months in the TN spirometry delivery model and the UC spirometry delivery model were compared and confidence interval for the difference was calculated using a formula that relies on the normal approximation to the binomial distribution.

P_{TN} overall = 0.587

P_{UC} overall= 0.077

Difference = 0.51 (95% Confidence interval 0.474 to 0.546)

Z = 0.51/0.018 = 28.33

$p < 0.0001$

6.2.4.2 Comparison of coverage of patients in target group attending for at least one consultation during six months in TN and UC models of spirometry delivery

To assess how complete the coverage of the TN spirometry delivery model was through the two spirometry sessions conducted per week, method 1 was used to estimate the total number of patients in the target group who had at least one consultation during six months in the TN period 1 practices (see Section 6.2.3.2.2). The proportions were estimated at 26% in practice 1, 41% in practice 3, 9% in practice 5 and 6% in practice 8. The median percentage tested in TN practices was 27% (IQR 27) and 7% in UC practices (IQR 14.3). Thus although these proportions are estimates only, a comparison indicates that a significantly larger proportion of the whole target group population was tested in TN practices than in UC practices during a six-month period (p=0.02 using Mann-Whitney test).

6.2.5 Comparison of target group participants in TN and UC models (Table 6.9)

Demographic profiles for gender, age, smoking history and current smoking status in both practice groups were similar although significantly more participants in TN practices did not report a respiratory diagnosis. Functional dyspnoea was present in a high proportion of participants in both TN and UC and of these significantly more participants in UC practices were graded at MRC grade 4. Significantly fewer participants in TN practices reported using an inhaled medication currently while

FEV1 as a percentage of predicted normal was significantly higher in participants in TN practices.

6.2.6 Classification of spirometry

6.2.6.1 Classification of spirometry by algorithm in target group participants in TN and UC models

In target group participants (n=615), 612 spirometry tests included at least one result of sufficient quality to be classifiable using the algorithm (Table 6.9).
When classified by a physiologist, overall 51% had normal lung function (NLF), 42% had obstructive lung function (OLF) and 8% had restrictive lung function (RLF). The distribution of proportions was not significantly different between TN practices and UC practices (p =0.20).

6.2.6.2 Proportions of target group participants in TN and UC models with airflow obstruction

In addition, the proportions of participants in both models for whom the ratio of FEV1/FVC was less than 0.7 were compared. In this study, FEV1 was measured on a single occasion without the administration of a bronchodilator. Thus, pre-bronchodilator ratio FEV1/FVC <0.7 was used to define airflow obstruction (AO). Overall, 146 (25.2%) participants in the target group had AO using this criterion (Table 6.9). Although a higher proportion of participants in UC practices had AO (33.3%) than in TN practices (24.0%), the difference in proportions between practices did not quite reach statistical significance (p =0.06). However for participants with AO, using the severity of airflow obstruction classification levels specified in GOLD guidelines (10), the proportion with mild obstruction (41%) in TN practices was significantly higher than in UC practices (31%) (Fisher's exact p=0.02) (Table 6.9).

Table 6.9: Characteristics of target group participants and spirometry results in TN and UC practices

Participants		*TN* *n=531*	*UC* *n=87*	p value
Males (%)		258 (48.6)	41 (47.1)	0.80[1]
Current smokers (%)		204 (38.4)	32 (37.6)	0.79[1]
Age (years)[†]		57.4 (13.4)	57.6 (12.1)	0.92[3]
Smoking history (pack years)[‡]		26.1 (27.3)	35.6 (31.4)	0.13[2]
FEV1 % predicted[†]		93.8 (20.8)	84.3 (26.8)	0.002[3]
No respiratory diagnosis (%)		386 (73.0)	28 (34.1)	<0.0001[1]
No functional dyspnoea (%)		129 (24.6)	12 (16.7)	<0.05[1]
MRC grade 1 or 2 (%)		268 (51.1)	25 (34.7)	<0.05[1]
MRC grade 3 (%)		55 (10.5)	7 (9.7)	NS
MRC grade 4 (%)		72 (13.7)	28 (38.9)	<0.0001[1]
% Using inhaled medication		78 (14.7)	36 (43.9)	<0.001[1]
Algorithm classification[§] (%)	OLF	218 (41.1)	39 (44.8)	0.20[1]
	NLF	275 (51.8)	37 (42.5)	
	RLF	36 (6.8)	10 (11.5)	
Airflow obstruction (%)	AO	127 (24.0) (n=127)	29 (33.3) (n=29)	0.06[1]
Classification of severity [‡5] (%)	Mild	52 (40.9)	9 (31.0)	0.02[4]
	Moderate	59 (46.5)	13 (44.8)	
	Very/severe	16 (12.6)	7 (24.1)	

(Data presented as [†] mean and SD, [‡] median and IQR, [§] n=615 for spirometry classification by algorithm, [‡] n=156 for classification by presence of AO. Statistical tests: [1] Chi-squared, [2] Mann-Whitney U-test, [3] *t* test, [4] Fishers's Exact. [5] Classification of severity based on GOLD criteria for FEV1% predicted (10,54))

6.*2.7 Feasibility of spirometry in TN delivery model (Table 6.10)*

In trained nurse practices, 532/785 (68%) participants in the target group who were approached agreed to spirometry. Responses to questions on reasons for agreeing were available from 524 participants (7 missing data). The commonest reasons for participants agreeing to spirometry were because they wanted to know their lung function or wanted a check-up, though nearly a quarter said they were worried about their lungs. Among participants that agreed to testing, 13% gave "wanting to assist research" as a specific reason for having spirometry.

An invitation for opportunistic spirometry was refused by 253 (32%) participants. Most participants refusing spirometry did not complete a full questionnaire, so only limited analyses were possible. However, there was no significant difference in the mean ages of those tested and those who refused spirometry (56.7 v 58.9 years, p=0.21). Compared to those undergoing testing, significantly more refusers were male (58% v 48%, p =0.03) or ex-smokers (70.7% v 61.8%, p =0.03). Reasons for refusing were available for 251 participants (1 case missing). Over 70% of those who declined gave a reason other than one of those offered in the questionnaire. The two most frequently cited were:

1. Lack of time
2. Feeling too unwell.

Only 26% of participants indicated they were not interested in knowing their lung function while 21% indicated they thought their lungs were normal.

Table 6.10: Responses to opportunistic spirometry invitation in TN practices
(Multiple responses permitted)

Reasons given by participants (%)			
Participants: spirometry performed	n=524 (%)	Participants: refused spirometry	n=251 (%)
Like to know lung function	341 (65.1)	Not interested in knowing	64 (25.5)
Check up	315 (60.6)	Think lungs are OK	52 (20.7)
Worried about my lungs	123 (23.4)	Result might worry me	17 (6.8)
Saw a poster	95 (18.1)	Do not like having tests	13 (5.2)
Family or friend asked me	19 (3.6)	Other- patient specified	176 (70.1)
Other- patient specified	68 (13.0)		

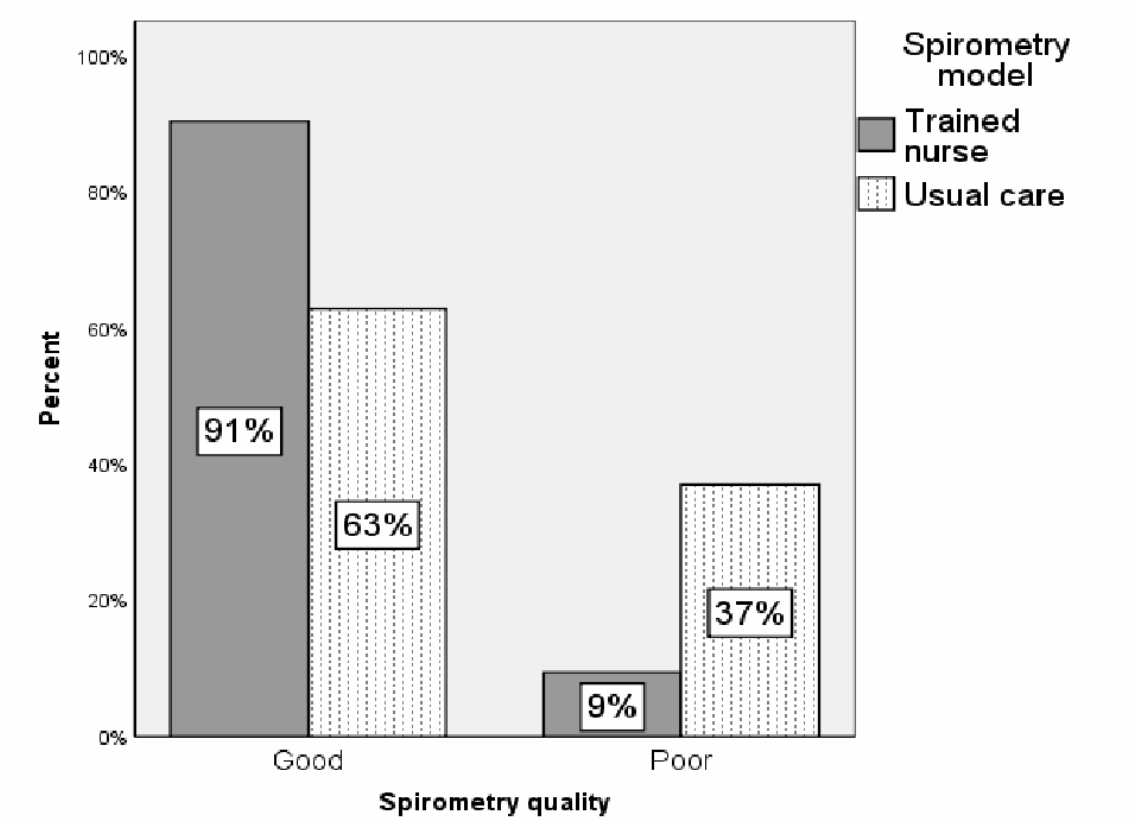
6.2.8 Comparison of spirometry quality

In TN practices 64% of spirometry was of Grade A compared to 38% of spirometry in UC practices (p <0.0001). Overall, a significantly higher proportion of tests performed in TN practices were of "good" quality (Grades A-C) compared to UC practices (91% versus 63%, p <0.0001) (Figure 6.3). The proportion of spirometry tests that had no acceptable result (Grades F) was only 1.5% in TN practices and 7.9% in UC practices.

There was significant variability in the proportion of tests of good quality within practices in the UC delivery model. Of the practices (2,4,6) that performed more than 5 tests, 48%, 72% and 70% were of good quality. However, in each of these practices the proportion of good quality tests showed a pattern of increasing as the six-month study period progressed and as a larger number of tests were performed each month. This was especially marked in practice 4 in which GPs performed spirometry for the initial three months until a practice nurse was employed and undertook spirometry testing. The proportion of good quality tests rose from under 20% to over 90%.

In the TN delivery model, two trained nurses visited two practices each. In practices 1 and 5, 94% of tests were of good quality while in practices 3 and 8, 85% were of good quality. Although there was a significant difference in proportions (p =0.001) both operators achieved high proportions of good quality tests.

Figure 6.2: Comparison of spirometry quality in TN practices and UC practices



(Good = Grades A-C, Poor = Grades D, F)

(Grade A= three acceptable tests & difference between best 2 FEV and FVC =<150 ml)

(Grade B= three acceptable tests & difference between best 2 FEV and FVC =< 200 ml)

(Grade C= two acceptable tests and difference between best 2 FEV and FVC =< 250 ml)

(Grade D= at least two acceptable trials but not reproducible or only 1 acceptable trial)

(Grade F= no acceptable test available.)

6.2.9 Time taken to perform spirometry

In TN practices, the median time for completion of a test to acceptable ATS standard was 5 minutes (range 3-14). The median number of attempts required to achieve an acceptable result, unless the participant was unable to continue, was 4 (range 3-10). No data on the time taken to perform spirometry was recorded systematically in UC practices. During discussions with practice personnel in practice 2, it was commented that a 15-minute appointment with the practice nurse was too short for spirometry and it generally required 20 minutes. The median number of attempts made per test was 3 (range 1 to 8).

6.2.10 Comparison of spirometry classification by trained nurse and respiratory physiologist

The results of application of the algorithm by the trained nurses and by a physiologist was compared for all spirometry performed in both TN and UC practices (n=699) where at least one acceptable quality test was available, 691 spirometry results. There was good agreement on classification into categories assigned by the two trained nurses and a physiologist (Kappa 0.92, $p < 0.001$).

6.2.11 Spirometry testing outside the target group

Spirometry was also performed on 20 participants in TN practices at the request of doctors during a consultation. Their mean age was 46 years (SD 18), 17% were smokers and 11% reported a diagnosis of asthma.

Doctors in UC practices carried out testing on 64 participants outside the target group criteria, with a mean age of 41 years (SD 20), 15% current smokers and 34%with a diagnosis of asthma reported.

6.2.12 Target group participants by spirometry classification

Data on participants in both TN and UC practices were pooled to compare the characteristics of spirometry algorithm groups and participants with airflow obstruction.

6.2.12.1 By spirometry algorithm (Table 6.11)

Participants classified with normal lung function (NLF) were younger, had a lower percentage of current smokers (36%) and a shorter smoking pack year history than those with obstructive (OLF), and although they were less likely to report a diagnosis

of lung disease or be using inhaled medication, 14% did report a respiratory diagnosis and 10% were using an inhaled medication. In the NLF group, asthma was reported by 9%, COPD by 2% and chronic bronchitis by 3%. As would be expected, the NLF group had the highest proportion of participants reporting no dyspnoea on exertion (32%).

In the OLF group a diagnosis of asthma was reported by 25%, COPD by 15% and chronic bronchitis by 9%. The proportion of participants who were still smoking was highest in the OLF group (42%).

There were only 46 participants in the RLF group. The mean age and smoking history were greatest for participants in this group although the proportion still smoking was lowest (24%). A diagnosis of lung disease was reported by 40% of the RLF group, COPD in 18% and asthma in 15%.

There was no significant difference between the OLF and NLF groups for participants' self-rated general health but participants' in the OLF and RLF groups had rated their lung damage due to smoking as significantly worse than those in the NLF group. The greater perceived lung damage in the OLF and RLF group was consistent with the lower mean FEV1 % predicted in these participants compared to the NLF group.

6.2.12.2 By presence of airflow obstruction (AO) (Tables 5.12 and 5.13)

As expected in the group with AO, mean FEV1 % predicted and mean $FEF_{25-75\%}$ % predicted were significantly lower than in those without AO. A higher proportion of participants with AO had symptoms of breathlessness although 25% of those without AO still had functional dyspnoea of MRC grades 3 or 4. The criterion for AO identified a group with more severe airflow limitation than the OLF criteria, by mean FEV1 % predicted (AO 72% compared to OLD 79%) and mean $FEF_{25-75\%}$ % predicted (AO 28% compared to OLF 35%) (Tables 6.11and 6.12)

Participants in the AO group did not have significantly lower self-rated general health than those without AO, but their self-rated lung damage due to smoking was significantly worse.

Data were missing for some participants on self-reported diagnosis (5%) and use of medication (3%). Based on those with responses, at least one respiratory diagnosis was reported by 49% of participants in the AO group and 19% of those without AO. In the population of participants that reported a respiratory diagnosis (Table 6.13), COPD was reported by only 32% of those with AO, but in addition 23% of those

without AO reported having COPD. Chronic bronchitis was the diagnosis reported by 26% with AO and 16% without AO. Asthma was the most commonly reported diagnosis, reported by 55% of those with AO and 64% of those without AO. For none of the diagnoses examined was the difference in proportions statistically significant. A diagnosis of asthma was also reported by 11.4% of those who reported COPD.

Similarly in the population that reported a respiratory diagnosis, overall the most frequently used medication was a short-acting inhaled beta-2 agonist agent (42%) followed by inhaled corticosteroids (15%), combination inhaled corticosteroids with long-acting beta-2 agonist (10%) and tiotropium (8%).

Use of all classes of inhaled medication was higher in those classified with AO compared to those without AO, although the difference in proportions was only statistically significant for tiotropium and long-acting beta-2 agonists (Table 6.13).

Table 6.11: Characteristics of target group participants by algorithm category

	OLF (n=257)	*NLF (n=312)*	*RLF (n=46)*	*p value*
Age (years)†	61.0 (12.5)	52.9 (12.3)	67.9 (12.6)	<0.0001[5]
Males (%)	115 (44.7)	157 (50.3)	24 (52.5)	0.36[1]
Current smokers (%)	108 (42.0)	113 (36.2)	11 (23.9)	<0.05[1]
Smoking history (pack years)‡	32 (31.9)	22.2 (25.2)	36.8 (33.0)	<0.0001[3]
No dyspnoea (%)	43 (17.0)	95 (31.9)	3 (7.1)	<0.0001[4]
MRC dyspnoea grade†	2.04 (1.8)	1.05 (1.3)	2.9 (1.3)	<0.0001[3]
Self-rated general health (VAS)‡	63.5 (30)	60 (30)	50 (63)	0.27[3]
Self-rated lung damage (VAS)‡	59 (50)	50 (40)	60 (61)	<0.01[3]
FEV1 % predicted†	79.0 (18.4)	107.1 (13.2)	65.3 (12.2)	<0.0001[5]
$FEF_{25-75\%}$ % predicted†	35.1 (13.7)	82.4 (20.0)	43.8 (17.1)	<0.0001[5]
Report diagnosis lung disease (%)	105 (43.0)	41 (14.2)	17 (39.5)	<0.0001[1]
Using inhaled medication (%)	80 (32.1)	29 (9.9)	5 (11.6)	<0.0001[1]

Table 6.12: Characteristics of target group participants by presence of airflow obstruction (AO)

	AO (n=156)	*No AO (n=460)*	*P value*
Age (years)†	62.9 (13.0)	55.6 (13.0)	<0.001[6]
Male (%)	80 (51.3)	218 (47.4)	0.40[1]
Current smoker (%)	63 (40.4)	171 (37.2)	0.48[1]
Smoking history (pack years)†	48.8 (36.8)	41.2 (34.1)	0.03[6]
No dyspnoea (%)	17 (11.2)	124 (27.9)	<0.0001[1]
MRC dyspnoea grade†	2.3 (1.3)	1.7 (1.4)	<0.0001[2]
Self-rated general health (VAS)‡	57.0 (35)	61 (30)	0.24[2]
Self-rated lung damage (VAS)‡	64 (49)	50 (45)	<0.0001[2]
FEV1 % predicted†	72.0 (20.0)	98.8 (18.1)	<0.0001[6]
$FEF_{25-75\%}$ % predicted†	27.5 (12.3)	70.4 (24.6)	<0.0001[6]
Report diagnosis lung disease (%)	76 (48.7)	89 (19.3)	<0.0001[1]
Using inhaled medication (%)	57 (36.8)	57 (12.5)	<0.0001[1]

(Data presented as † mean and SD, ‡ median and IQR. Statistical tests: [1] Chi-squared, [2] Mann-Whitney U-test, [3] Kruskal-Wallis test, [4] Fisher's Exact, [5] Anova, [6] T-test.)

Table 6.13: Participants reporting a diagnosis of respiratory disease: diagnosis and use of medication by presence of airflow obstruction (AO)

	AO *n=76 (%)*	*No AO* *n=89 (%)*	*p value*
Diagnosis:			
COPD	24 (31.6)	20 (22.5)	0.19[1]
Chronic bronchitis	20 (26.3)	14 (15.7)	0.09[1]
Asthma	42 (55.3)	57 (64.0)	0.25[1]
Another lung disease	7 (9.2)	7 (7.9)	0.74[1]
Inhaled medication:			
SABA	36 (47.4)	33 (37.1)	0.14[1]
Ipratropium	3 (4.0)	3 (3.4)	1.0[4]
Tiotropium	10 (13.2)	3 (3.4)	0.02[4]
LABA	4 (5.3)	0 (0)	0.04[4]
ICS	14 (16.9)	11 (2.4)	0.19[1]
Fixed combination ICS/LABA	10 (13.2)	6 (6.7)	0.16[1]

(Data presented as [†] mean and SD, [‡] median and IQR. Statistical tests: [1] Chi-squared, [4] Fisher's Exact. SABA= short-acting inhaled beta-2 agonist, LABA= long-acting inhaled beta-2 agonist, ICS= inhaled corticosteroid)

6.2.12.3 By presence of airflow obstruction (AO) in participants with OLF

The utility of the algorithm in identifying early obstruction was assessed by comparing participants classified with OLF who met the criterion for airflow obstruction (AO) (56.8%, n=146) with those who did not (43.2%, n=110) (Table 6.14).

Participants with OLF but without AO were slightly younger that those with AO, though the difference was not quite statistically significant (p=0.05). Most had functional dyspnoea (75%) but breathlessness graded on the MRC scale was significantly less severe than in those with AO. In those without AO, respiratory diagnosis and inhaled medication use were reported by 30% and 20% respectively, with a diagnosis of COPD reported by 10%.

FEV1 < 80% predicted in 62% of participants with AO but only 15% of those without AO. However, the reduced mean mid-expiratory flow ($FEF_{25-75\%}$) in those in the OLF group without AO (46% predicted) indicates small airways disease was common in these participants.

Table 6.14: Characteristics of participants classified with OLF using the algorithm by presence of airflow obstruction (AO)

	OLF and AO (n=146)	*OLF without AO (n=110)*	*P value*
Age (years)†	62.3 (12.5)	59.2 (12.3)	0.05[6]
Male (%)	71(48.6)	44 (39.6)	0.15[1]
Current smoker (%)	60 (41.4)	47 (42.3)	0.84[1]
Smoking history (pack years)†	40.5 (32.3)	37.0 (29.3)	0.41[6]
No functional dyspnoea (%)	15 (10.5)	28 (25.5)	<0.01[1]
MRC dyspnoea grade†	2.2 (1.3)	1.8 (1.4)	<0.01[6]
Self-rated general health (VAS)†	60.2 (24.2)	64.7 (22.6)	0.16[6]
Self-rated lung damage (VAS)†	65.2 (30.7)	54.3 (29.0)	0.03[2]
Self-rated quit benefits (VAS) ‡	95 (13)	100 (8)	0.16[2]
Report diagnosis lung disease (%)	74 (53.2)	31 (29.5)	<0.0001[1]
Report COPD (%)	23 (22.3)	9 (10.1)	0.02[1]
Report chronic bronchitis (%)	20 (13.8)	4 (3.7)	<0.01[1]
Report asthma (%)	42 (28.8)	22 (20.2)	<0.01[1]
Using inhaled medication (%)	57 (39.3)	23 (20. 9)	<0.01[1]
Lung function			
Ratio FEV1/FVC†	0.60 (0.09)	0.73 (0.03)	<0.0001[1]
FEV1 % predicted†	71.6 (19.9)	88.7 (10.0)	<0.0001[6]
FVC % predicted†	93.1 (20.2)	96.7 (12.2)	0.46[6]
$FEF_{25-75\%}$ % predicted†	26.7 (11.5)	45.9 (7.4)	<0.0001[6]
Participants FEV1 <80% predicted (%)	90 (62.1)	17 (15.3)	<0.0001[1]

(Data presented as † mean and SD, ‡ median and IQR. Statistical tests: [1] Chi-squared, [2] Mann-Whitney U-test, [6] *t* test.)

6.*2.13 Time to detect airflow limitation in TN spirometry delivery model*

Based on data for the time taken to complete a spirometry test (see section 6.2.6), with 42% of results classified as OLF in the target population, one participant with OLF was detected in 11 minutes of actual time spent performing tests. AO was classified in 24% of the target population, thus one participant with AO was detected in 21 minutes of time spent on opportunistic testing.

6.2.14 Comparison of costs of spirometry in TN and UC models

For six months opportunistic testing in the TN model the total cost of spirometer equipment, the salary and travel costs of trained nurse sessions was $42,404 (Table 6.15). Study costs in the UC model included the provision of spirometry equipment, the salary and travel costs for monthly spirometer calibration checks in practices, a total of $6,266. This does not include the cost, borne by the practices, of any practice-based nurses' salaries, which should be included to make a direct comparison of equivalent costs.

However, based on the costs shown in Table 6.15, the cost per spirometry test performed was $77 in the TN model and $108 in the UC model. The cost per participant with AO was $334 in the TN model and $561 in the UC model.

Cost effectiveness calculations based on the frequency of recognition of new cases of COPD are shown in later in section 6.2.13.5.3.

Table 6.15: Spirometry costs in TN and UC delivery models ($AUS).

	TN practices	*UC practices*
Spirometers	$3,500 x 2	$3,500 x 4
Spirettes	$1,600	$415
TN time cost	$32,292	$1676 (calibration only)
TN travel costs	$1,512	$175
Total	$42,404	$16,266

6.2.15 Focus groups

6.2.15.1 GP participation in focus groups

All focus groups were held on practice premises, during non-consultation periods, either at the start of the day or during the mid-day break. Each commenced with light refreshments in a communal meeting room or vacant office. Group size varied as shown below but in every group all GPs present contributed to the discussions. After an initial open question about the model of spirometry that had been used in the practice, the order of topics covered generally flowed from the GPs, but the facilitator guided and prompted discussion to ensure all question topics were covered. The facilitator presented the clinical scenarios to participants and used the first open question to stimulate discussion. The questions were phrased to elicit information on participants' confidence in making a diagnosis, the usefulness of the spirometry result in making a diagnosis and in discussions with a patient. No direct question was asked on the nature of the diagnosis. There were frequent interactions between doctors, sometimes to reinforce a contribution by another participant, to clarify and interpret something that had been said or sometimes to offer a differing view from their experience. Some doctors expressed stronger views that were related to their specific interest in prevention of a particular chronic disease or their expertise in chronic lung diseases.

In TN practices there were 30 GPs working either full-time or part-time. Three focus groups were held in TN practices with 15 GPs participating in total (practice 1, n=6 GPs; practice 3, n=6 GPs; practice 5, n=3 GPs). Practice 8 was approached on four occasions to offer a focus group but no positive response was received.

In UC practices, there were 19 GPs working either full-time or part-time. Three focus groups were held in UC practices. Practice 7 shared a common administration with practice 3 and the GPs routinely held joint practice educational events. In total, 14 GPs participated (practice 2, n= 6 GPs, 1 PN, 1 practice manager; practice 4, n= 3 GPs; practice 6, n= 3 GPs; practice 7, n= 1 GP who attended a group in practice 3).

6.2.15.2 Process of coding during thematic analysis

As each transcript was read, initial codes were allocated. These codes emerged from the data but the process was informed by the research hypotheses around which the intervention study was designed, in order to evaluate the spirometry delivery models. Codes were subsequently grouped into categories and these evolved into themes, for

example on the usefulness, practicality and drawbacks of spirometry delivery models.

6.2.15.3 Major themes

The major themes emerging from focus group discussion on the experience of GPs on the model of spirometry delivery used in their practice in the initial six months are summarised in Table 6.16. An indication of whether the theme was rated as important by GPs who experienced the TN or UC models of spirometry provision is given. Major themes are illustrated with quotes from GPs, with an indication of the spirometry model they experienced (TN or UC), in sections that present the individual themes.

Table 6.16: Summary table showing comparison of themes in the analysis of focus groups with general practitioners by models of spirometry delivery

Themes	*TN*	*UC*
Essential that spirometry is of high quality	Yes	Yes
GPs lack time to perform good quality spirometry	No	Yes
GP initiation of test not required	Yes	No
Nurse performed spirometry less threatening for patients	Yes	Yes
Need for systematic follow up	Yes	No
Lack of “ownership” by GP of test result	Yes	No
Valuable for diagnosis of lung disease	Yes	Yes
Objective measurement of lung function useful in future	Yes	No
Emphasis on clinical basis for diagnosis of respiratory disease	Yes	Yes
Uncertainty about value of using the label COPD	Yes	Yes
Uncertain of spirometric criteria for COPD	Yes	Yes
Identifying smokers	Yes	Yes
Reminder to update smoking status in records	Yes	Yes
Initiation of discussion on smoking cessation	Yes	Yes
Personalise quit advice	Yes	Yes
Normal spirometry result decreasing motivation to quit	Yes	Yes
Cost disincentive without appropriate Medicare funding	Yes	Yes

(TN= trained nurse model, UC= usual care)

6.2.15.3.1 Quality of spirometry

GPs in both models agreed testing was only of any value if performed to a high standard.

> *"It seems quite critical, that the person doing the actual testing is trained, and is aware of things like a patient's technique that is not correct" TN-GP*

Lack of time was named as a limitation to performing spirometry. GPs in UC practices emphasised the great difficulty in doing spirometry personally and universally saw this as a role for a practice nurse:

> *"You'd have to use it all the time to get really efficient" UC-GP*

> *"Whether the practices have got practice nurses is going to make a huge difference I think, to how easy it is to introduce spirometry into practice regularly" UC-GP*

> *"Given the general level of busyness of the practice, that (spirometry) is a problem, working in a time for the patient to come back and specifically have it" UC-GP*

However, the time required to obtain good quality spirometry meant it took longer to perform than was initially thought:

> *"They (spirometry tests) took a while didn't they? They became half an hour appointments not fifteen minutes very quickly" UC-GP*

6.2.15.3.2 Initiation of spirometry

The opportunistic nature of testing in TN practices was seen by GPs as an advantage because generally in clinical practice, spirometry would only be initiated if they were already aware of a clinical respiratory problem:

> *"I like having (opportunistic spirometry), because I probably wouldn't be requesting spirometry, unless I already knew there was a problem" TN-GP*

GPs' enthusiasm for testing in UC practices was high initially after receiving training, but tended to wane with time and the realisation that it was both time consuming and difficult to achieve high quality results.

6.2.15.3.3 Acceptability to patients

Spirometry was rated by GPs in the TN practices as highly acceptable to patients. Opportunistic spirometry was felt to have major advantages over GP initiated spirometry for convenience and acceptability to patients, especially for those that smoked, who might be reluctant to raise concerns over respiratory symptoms with GPs because of guilt associated with feeling that the damage was self-inflicted:

> *"She (TN) is not too authoritarian" TN-GP*

> *"Very non threatening" TN-GP*

> *"I am sure (spirometry) is acceptable, if it seems to be someone asking you very pleasantly if you would like to do a test, in a non-judgemental way" TN-GP*

6.2.15.3.4 Follow up of spirometry

GPs in both groups emphasised there was a need for a specific follow-up consultation about the results. Finding the time required to follow up spirometry results created difficulties in both groups of practices, with the practice workload already heavy. It was noted that this was also an issue for follow up of tests in other conditions. Effective follow up might be delayed or prevented as other aspects of the consultation had higher priority for the patient or the GP:

> *"The patient would actually need to have an appointment specifically to follow that up. Because otherwise it is fitted in amongst what ever else is of primary concern to them, and so it tends to go to the bottom of the heap" TN-GP*

> *"Then working in a time for them to come back and talk about it, all of that might be at the next consultation. It is hard to work it in." UC-GP*

In TN practices there were concerns over the "ownership" of a test not initiated by a GP that fell outside normal practice processes for communication and storage of results:

> *"Whereas if I order a test I have some obligation to follow up the results and discuss it with the patient" TN-GP*

There were concerns over the medico-legal implications if proper follow up was overlooked:

> *"Normally for medico-legal purposes, all results get put on the patient's file. Because we haven't ordered it, it doesn't come back to the doctor"TN-GP*

These problems were amenable to clarification of protocols with clerical staff:

> *"You just make sure that it happens. You just put systems into place so that things do get followed up." TN-GP*

6.2.15.3.5 Use in diagnosis of lung disease

GPs in both models saw the value of having a record of a patient's lung function for the immediate diagnosis of lung disease:

> *"Well, it helps you in making a diagnosis and helps you to quantify the degree of damage" TN-GP*

> *"I am looking for a reason why they are short of breath" UC-GP*

> *"Just whacking the stethoscope on is not good enough anymore" UC-GP*

In an individual scenario however, the need for spirometry was questioned, with a number of GPs giving more weight to symptoms or even feeling that the clinical picture alone would enable them to make the diagnosis:

(Researcher: "Which particular part of it is the most important for you?" "In a lot of ways the history. That's what really should clue us to everything else in a sense" UC-GP

"From the (clinical) information you know that she is going to have COPD, even if you didn't look at that (spirometry) from the fact that she has been smoking for 32 years and she's short of breath." UC-GP

Spirometry was justified though for its value in reinforcing a message to the patient:

"But this is something physical to put in front of her." UC-GP

When looking at spirometry results, GPs in both practice groups described use of spirometry results in the context of other clinical patient information, such as symptoms and activity limitations. There was a strong sense whenever GPs discussed individual patients, that they took a holistic view of the patient and their overall health in the family and social context:

"You can use spirometry to stimulate management of wellness in general, rather than just what is going on in the lungs" TN-GP

6.2.15.3.6 Diagnosing COPD

Discussion on the diagnosis of COPD was particularly stimulated through the use of two scenarios. One was of a female smoker, aged 57 years, with a smoking history over 30 pack years, reporting breathlessness when walking for 100 metres or only a few minutes (MRC grade 4). She gave a very low self-rating of her general health and she rated the damage to her lungs from smoking as extremely severe. She knew there were great benefits for stopping smoking. Her lung function showed moderate COPD, FEV1/FVC ratio = 0.63, FEV1 = 64% predicted.

The second was a male smoker aged 47 years, with a smoking history of 32 pack years, reporting breathlessness when hurrying or on a slight hill (MRC grade 2). He had an average self-rating for his general health, and his rating of lung damage from smoking was moderately severe but thought there were great benefits from quitting. Lung function showed small airways disease and did not meet the criteria for COPD, FEV1/FVC ratio = 0.71, FEV1 99% predicted, $FEF_{25-75\%}$ = 52% predicted.

A striking feature in all focus groups was the very infrequent use of the term COPD by participating doctors. As previously stated, its use was avoided during presentation of the clinical scenarios and spirometry results in order to explore the issue of doctors' use of a label.

When considering the scenario for the patient who had spirometry typical of moderate COPD, various terms were used as labels included "reduced lung function", "obstructive" and "respiratory problem". Only in one case was there an emphatic diagnosis given:

> *"Diagnostically this seems to be COPD" UC-GP*

Variation in the terminology used for chronic respiratory diseases over time was felt to be confusing for patients and patients' unfamiliarity with the current term COPD, contributed to its avoidance by most doctors when discussing what they would say to the patient. One doctor said:

> *"She has got reduced lung function and it's probably due to smoking." TN-GP*

Another said:

> *"You can support what you already know, she is developing a respiratory problem with her smoking" TN-GP*

Then when asked for some clarification, the GP specified emphysema, while noting that the patient would understand it better than COPD:

> *"I think you would have to tell her that she has got emphysema, because that is what she would understand" TN-GP*

Another doctor supported this, emphasising the need for a patient to understand the implications of a diagnostic term:

"A lot of the medical terms, especially the variable ones, they just drift by, they make no sense to them so they don't apply them. They don't know what it means" TN-GP

The value of a label was also questioned under every circumstance. It was thought to be more valuable if it increased the probability of behaviour change in patients, but less valuable in the absence of curative therapy for a disease, such as in COPD. Doctors felt they needed to ensure there was good understanding if they gave a diagnostic label to patients so they would take appropriate action:

"And the course of action would be smoking cessation". UC-GP

"You diagnose them with anything that's got a label and a treatment, it gives them much more incentive to do something about it". TN-GP

The label was contrasted with making the message effective:

"I mean if you give them a label or not, I think it depends on what impression you give of how serious it actually seems to be, rather than just a label." TN-GP

GPs varied in their knowledge of spirometric indices of obstruction, with most unsure of the basis for classifying COPD. A preference for clinical assessment over guideline criteria was expressed, especially where the abnormality on spirometry was less severe:

"Definitions are only guidelines for us of course, and at each clinical interview there are all sorts of other things going on." TN-GP

Many found the value of the result lay more in viewing the flow-volume curve and demonstrating an abnormality to their patient:

"The most useful bits are the graphs because they are the easiest to interpret and also they are education. You can say to the patient 'Look here is where you should be'" UC-GP

There was agreement that GPs needed assistance with the interpretation of lung function parameters measured by spirometry. Developing expertise within the practice (beyond current level of training) or receiving an interpretation from a specialist physiologist were suggested as potentially valuable ways of supporting in-house spirometry practice:

> *“It would be really good if somebody had that as a sort of speciality” TN-GP*

> *"It would be good to have it actually reported, like a pathology result. You know ‘Abnormal- follow up recommended’. That would really help and then we would definitely act on that”. TN-GP*

Using spirometer software for automatic interpretation had been found, through past experience, to add little practical value.

6.2.15.3.7 Objective measurement

GPs, especially in TN practices, emphasised the possibility of on going monitoring of lung function and compared this to measurement of blood pressure to detect hypertension:

> *“It is something objective, and it is repeatable. You can see five years down the track or 10 years. I mean it’s a baseline measure” TN-GP*

In UC practices, GPs did not use spirometry for on-going management in COPD at present, but appeared to share the opinion that it would eventually become accepted as essential:

> *“It’s over to the toss of the coin as to how the patient goes and doing spirometry doesn’t really help us, unless there has been some sort of major change” UC-GP*

> *“I mean, we never think of managing a patient without taking their blood pressure. Perhaps years down the track you would never think twice about managing COPD without regular spirometry” UC-GP*

6.2.15.3.8 Cost limitations

GPs in both groups doubted the practicality of increasing spirometry use without improved Medicare funding, with the introduction of reimbursement for single occasion testing:

> *"Well, unless you are doing a full lung function test you can't claim anything back from Medicare anyway" UC-GP*

This would make the use of spirometry for case finding difficult:

> *"(The cost) is going to be itself a considerable disincentive for a lot of people, unless they are short of breath" TN-GP*

6.2.15.3.9 Identification of smokers

The most likely consequence of spirometry in both practice groups of GPs related to smoking cessation: They felt they would be prompted to identify patients' smoking status and update records. GPs admitted that before the study began, the proportion of patients' computer records patients with a completed recording of smoking status was very low. The performance of spirometry was used as an occasion to update the record in both groups of practices. This was seen as clinically valuable and helped to achieve a target for computerisation of medical records in practices 2 and 6:

> *"Sometimes I have been unaware those particular patients are smokers, or even ex smokers" TN-GP*

> *"I have identified a few patients who I didn't know were smokers. I always thought I could smell them" UC-GP*

> *"We've gone from about having three hundred smokers out of fifteen thousand files to five or six thousand I think at the moment, which is a bit more accurate" UC-practice manager*

6.2.15.3.10 Using spirometry to aid smoking cessation

Smoking was accepted as a hugely important issue for the health of their patients and all GPs said they would use spirometry to initiate discussion about smoking:

> *"It is always our intention to try and get them to cease and this area more than any other needs to limit cigarette consumption for all sorts of reasons, economic, social, health wise and all the other reasons" UC-GP*

> *"I guess that is an entry into talking about how to give up, or whether they want to give up" TN-GP*

GPs expressed some doubts about the value of spirometry under all circumstances, especially when no major abnormality was demonstrated. They named instances of a normal result being used to validate continuing smoking by a patient:

> *" 'No problems Doc. You don't need to talk to me about smoking. My lung test is perfect!' So they were getting in first, being forearmed, even before I start" UC-GP*

Here the participant could be seen as trying to prevent the GP giving further advice on smoking cessation rather than to deny the need to quit smoking, separating the smoking damage in the lungs in terms of airflow obstruction from other harmful effects. This emphasis was common among GPs, who tended to describe effects on the "whole person" not just the lungs.

Not all GPs were concerned about the potential for some patients to interpret receiving a normal spirometry result as permission to keep smoking. It was frequently pointed out by GPs that advice could be personalised and tailored to the individual patient's result:

> *"You know I wouldn't be totally concerned about people interpreting it that way. I mean the push is to say, 'OK you've been smoking for this long, obviously you are one of those robust characters who don't (have COPD). This will not pick up back but you know inevitably you will enter that slope. You haven't done so far, good time to give up before there is any damage'" UC-GP.*

"You can sort of leverage it a bit and try to get them on side" TN-GP

"You could certainly say that if she stopped smoking there is a good chance she won't get any worse, whereas if she keeps smoking you can guarantee she will" UC-GP

They would try to use the visual impact of an abnormal result to change the patient's attitude and increase their motivation, possibly with a description of living with lung damage, using the result to scare or frighten the patient:

"You'll be able to say to somebody, here is a real objective measure of why you should be giving up smoking. That slope has changed and although it's not ever going to go back to normal it's not going to go to this one which is the horrible one, which would have you carrying an oxygen cylinder around" UC-GP

All doctors agreed that an obviously abnormal result that could be demonstrated visually to the patient had "shock value" and they hoped this aspect might cause behaviour change:

"Sometimes they just need that extra kick just to give them a reason to stop" UC-GP

However, they were also sceptical about patients actively taking responsibility for their health and changing their behaviour as a result of tests in general which caused them to feel frustrated and powerless:

"People are always keen to have tests, they are just not nearly as keen to act on them. That is our frustration" TN-GP

6.2.16 Practice records data extraction

6.2.16.1 Participants eligible for data extraction

The classification algorithm was used to select participants for extraction of data from practice records (Chapter 4.10.2.1). Those classified with OLF or RLF (n=303)

and current smokers with NLF (n=102) were eligible. Records were actually reviewed for 368 participants (315 in TN practices and 53 in UC practices). The effect of spirometry on six-month consultation frequency (results already reported in section 6.2.3.2), the recording of smoking status (see section 6.2.16.10) and recording of advice from GPs to current smokers are based on this population (see section 6.2.16.11).

For those with OLF/RLF, follow up also included the impact of the provision of spirometry on subsequent GP workload, new diagnosis of COPD, investigations ordered and management of COPD. These data were extracted from 266 patient records, 226 in TN practices (89% of eligible participants) and 40 (81.6% of eligible participants) in UC practices for the period covering three months following spirometry (Table 6.17). Follow up was limited by availability of records at the time of visits to practices, but there were no significant differences in the proportions of participants whose records could be examined for data extraction between individual practices. Results from data extracted from the records of these participants are presented in sections 6.2.13.1 to 6.2.13.9.

6.2.16 2 Type of records used

The type of records used to extract data for eligible participants is shown in Table 6.18. In TN practices, both computer and paper records were used for 83.6% of participants. For a few participants (5%) who were relatively new to a practice, only paper records existed and for 12% paper records were unavailable and the only source was computer records on the day data were extracted. In UC practices 68% had only computer records in three practices that had ceased to use paper records.

Table 6.17: Completion of data extraction for eligible participants practices with TN and UC spirometry delivery models.

		Data extraction done		*Eligible*
	Category	No n (%)	Yes n (%)	
Trained nurse	OLF	20 (9.2)	198 (90.8)	218
	RLF	8 (22.2)	28 (77.8)	36
	Total	28 (11)	226 (89.0)	254
Usual care	OLF	7 (17.9)	32 (82.1)	39
	RLF	2 (20.0)	8 (80.0)	10
	Total	9 (18.4)	40 (81.6)	49

Table 6.18: Type of records used for data extraction in practices with TN and UC spirometry delivery models.

Type of records	*TN*	*UC*	*All*
	n=226 (%)	*n=40 (%)*	*n=266 (%)*
Paper	11 (4.9)	0 (0)	11 (4.1)
Computer	26 (11.5)	27 (67.5)	53 (19.9)
Paper+computer	189 (83.6)	13 (32.5)	202 (75.9)

6.2.16.3 Spirometry result availability

The presence of the spirometry test result in medical records was confirmed for 195 (86.2%) participants in TN practices and 30 participants (75.0%) in UC practices.

6.2.16.4 Follow-up consultations following spirometry

6.2.16.4.1 Non-consultation with GP following spirometry

In TN practices, 43 (19%) participants in the target group with abnormal spirometry (OLF or RLF) had no record of a GP consultation during the three months following testing. For those with OLF, 26 (13%) participants had not had a consultation in the three months following spirometry. In UC practices, 3 (6%) participants in the target group with abnormal spirometry had no record of a GP consultation during the following 3 months.

6.2.16.4.2 Frequency of GP consultations

The numbers of consultations by participants in the three months prior to and three months following spirometry were compared for both TN and UC practices. There was no significant difference in the median frequency of consultations pre-spirometry between participants in TN practices (2, IQR 3) and UC practices (2, IQR 2) (p=0.12). Post-spirometry the median frequency of consultations was again 2 (IQR 3) in both TN practices and UC practices (p=0.63). There was no change in frequency of consultations from before to after spirometry in either TN practices (p=0.70) or in UC practices (p=0.47).

6.2.16.5 Doctor-recorded respiratory diagnosis

6.2.16.5.1 Existing doctor-recorded diagnosis of respiratory disease

Recognition of COPD and other respiratory diseases was based on doctor-recording of the diagnosis in practice records (Table 6.19). Among those whose records were examined, prior to spirometry a significantly higher proportion in TN practices had no recorded diagnosis (72%) than in UC practices (38%), and a significantly lower proportion of participants had a doctor-recorded diagnosis of COPD in TN practices (7%) than in UC practices (33%) (p<0.001).

Prior to spirometry in the total target group population tested, doctor-recorded diagnoses were found of COPD in 3% and of asthma in 8% in TN practices, compared to 15% with COPD and 14% with asthma in UC practices (difference for COPD, p<0.001 and difference for asthma p=0.05). A higher proportion in TN

practices (46%) had no doctor-recorded respiratory diagnosis in comparison to UC practices where only 29% had no doctor-recorded respiratory diagnosis (p<0.01).

6.2.16.5.2 New doctor-recorded diagnosis of respiratory disease

New doctor-recorded respiratory diagnoses amongst the sample of participants who had data extraction are shown in Table 6.20 for participants in TN practices and Table 6.21 for those in UC practices.

Figure 6.4 shows how the diagnosis of COPD changed in all target group participants who underwent spirometry by either the TN or UC delivery model. Using the robust definition of the presence of airflow obstruction (AO = FEV1/FVC <0.7) in keeping with the criterion specified in guidelines for the diagnosis of COPD, the proportions of participants with AO who had a doctor-recorded diagnosis of respiratory disease were compared.

In TN practices, doctor-recorded diagnoses of COPD in the population of all target group participants increased after spirometry by 2.1% and in the population with actual AO by 7.1%. However, three months after spirometry, 66 (60%) participants with AO whose records were examined remained without a doctor-recorded diagnosis of COPD, asthma or chronic bronchitis. The severity of COPD in those participants in TN practices with a new doctor-recorded diagnosis was classified as follows: mild in 3 (27.3%), moderate in 5 (45.5%), severe in 2 (18.2%) and very severe in 1 (9.1%).

In UC practices, doctor-recorded diagnoses of COPD in the population of all target group participants increased after spirometry by 3.5% and in the population with AO by 6.9%. As mentioned above, more participants who had spirometry in this group already had a doctor-recorded respiratory diagnosis and thus a significantly lower proportion, only 7 (29%) participants with confirmed AO whose records were examined, remained without a doctor-recorded diagnosis of either COPD or asthma three months after spirometry. This proportion was significantly lower than in TN practices (p<0.0001). The severity of COPD in the three participants in UC practices with a new doctor-recorded diagnosis was classified as moderate.

Almost no increase in diagnoses of asthma was seen in either TN practices or UC practices, as might be expected without post-bronchodilator spirometry measurements.

In participants without previous doctor-recorded diagnosis, AO was found in 102 (33.9%) in TN practices and 17 (40.5%) in UC practices of whom 8 (7.8%)

participants and 2 (11.8%) participants had doctor-recorded COPD at follow up, in the respective groups.

A new doctor-recorded diagnosis of COPD was made in 2/116 (1.7%) participants in TN practices and 1/16 (6.3%) participants in UC practices when AO was not present according to the spirometry result (Figure 6.4).

Table 6.19: Pre-spirometry doctor-recorded respiratory diagnosis for participants with OLF and RLF for whom data were extracted from practice records by TN and UC spirometry model

Doctor-recorded diagnosis	*TN* *n=226 (%)*	*UC* *n=40 (%)*	*p value*
None	163 (72.1)	15 (37.5)	< 0.0001
COPD	16 (7.1)	13 (32.5)	< 0.0001
Asthma	34 (14.6)	9 (22.5)	0.21
Chronic bronchitis	2 (0.9)	1 (2.5)	0.39
Bronchitis	11 (4.9)	2 (5.0)	1.0

Table 6.20: Comparison of doctor-recorded respiratory diagnosis for participants with OLF and RLF for whom data were extracted pre- and post-spirometry in TN practices (n=226).

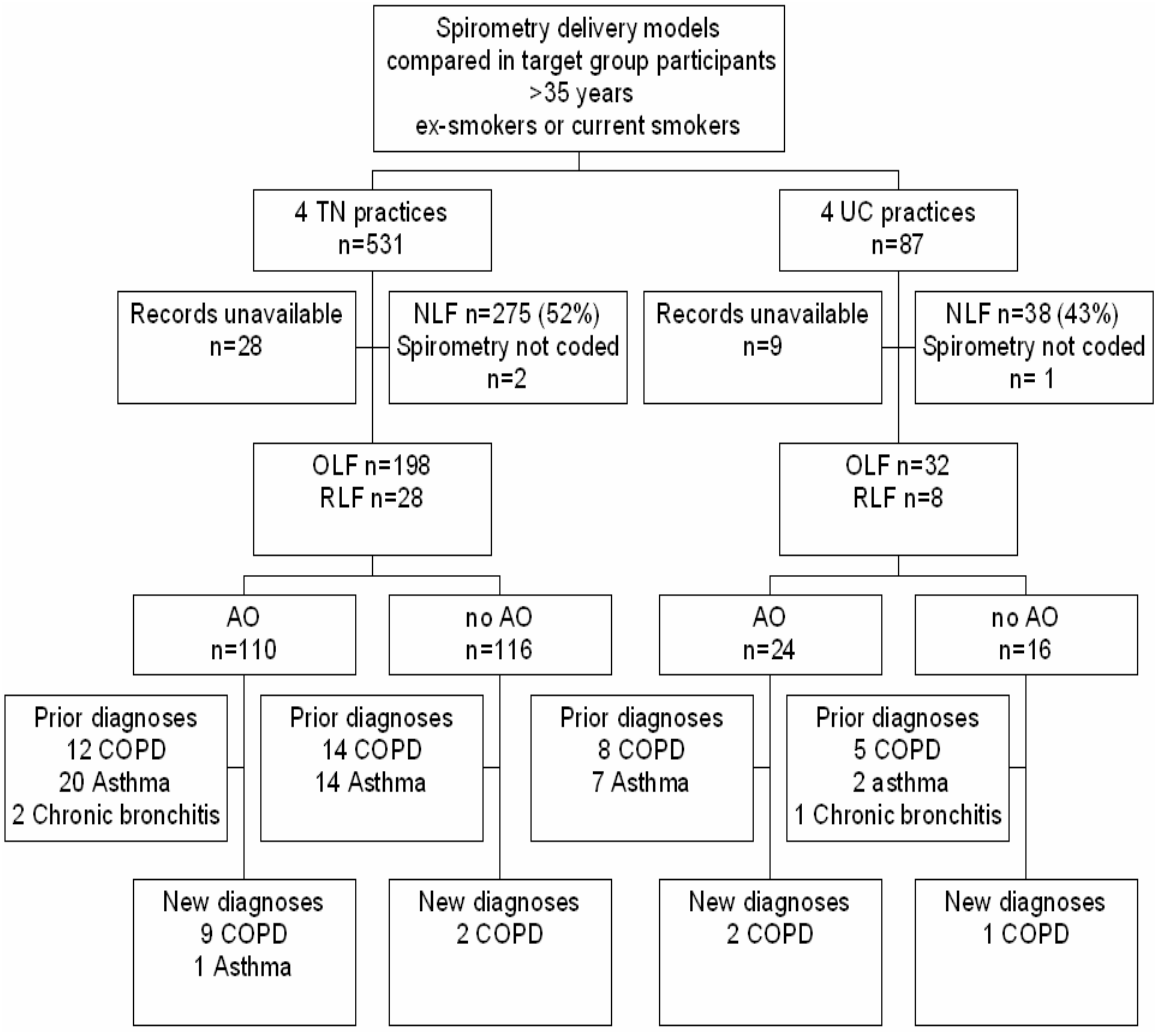
		Post-spirometry				
		None	Asthma	CB	COPD	Bronchitis
Pre-spirometry	None (n=163)	152	1	0	8	2
	COPD (n=16)	1	0	0	15	0
	Asthma (n=34)	2	27	0	3	2
	CB (n=2)	0	0	2	0	0
	Bronchitis (11)	7	0	0	0	4

Table 6.21: Comparison of doctor-recorded respiratory diagnosis pre- and post-spirometry for participants with OLF and RLF for whom data were extracted in UC practices (n=40).

		Post-spirometry				
		None	Asthma	CB	COPD	Bronchitis
Pre-spirometry	None (n=15)	10	1	0	2	2
	COPD (n=13)	0	0	0	13	0
	Asthma (n=9)	0	9	0	0	0
	CB (n=1)	0	0	1	0	0
	Bronchitis (n=2)	1	0	0	1	0

CB=chronic bronchitis

Figure 6.4 Impact of spirometry on doctor-recorded diagnosis of COPD in participants in practices with TN and UC spirometry delivery



(TN = trained nurse model, UC= usual care, NLF= normal lung function, OLF= obstructive lung function, RLF= restrictive lung function, AO= airflow obstruction, FEV1/FVC <0.7)

6.2.16.5.3 Cost of detecting new cases of chronic respiratory disease

The costs incurred in providing spirometry in the TN and UC practices are shown in section 6.2.11. Based on these costs, each newly detected case of doctor-recorded COPD/asthma cost $3,534 in TN practices and $5,422 in UC practices. However, if all participants with AO but without a prior doctor-recorded diagnosis of chronic respiratory disease were recognised, the cost per newly diagnosed case would be $558 in TN practices and $1,807 in UC practices in this study. In reality the cost of spirometers would be written down over a longer period of around 10 years thereby making the cost considerably less.

6.2.16.6 Prescribing respiratory medications

6.2.16.6.1 Prior to spirometry

Prior to spirometry in the population of participants with OLF/RLF who had data extracted from practice records, the frequency of prescribing respiratory medications was significantly higher in UC practices compared to TN practices for inhaled short-acting beta agonists, tiotropium, fixed-dose combination corticosteroid/long-acting beta agonist inhalers and ipratropium (Table 6.22). There was no difference in prescribing rates for inhaled corticosteroids, long-acting beta agonists or oral theophyllines between TN and UC practices. This is consistent with the proportion having a doctor-recorded respiratory diagnosis being nearly twice as great in UC practices (73%) as in TN practices. Inhaled short-acting beta agonists were the most frequently prescribed medication (45%), followed by inhaled corticosteroids (alone or in a combination with long-acting beta agonist, 25%) and tiotropium (20%) in UC practices.

There was no significant difference between TN and UC practices in the proportion of participants recorded as having either influenza immunisation or pneumococcal vaccine.

6.2.16.6.2 After spirometry

In TN practices there were small increases in number of participants prescribed combination ICS/LABA agents and tiotropium and small decreases in prescribing of inhaled corticosteroids, long-acting beta agonists and inhaled anticholinergic in TN practices, but no changes were statistically significant.

In UC practices, use of short-acting beta agonists, combination ICS/LABA agents, tiotropium and theophyllines increased. None of the changes was statistically

significant (tiotropium $p<0.18$ and FDC $p<0.18$). There was a small non-significant decrease in use of inhaled corticosteroids alone.

Annual immunisation in practices against influenza was not fully completed in practices at the time data were extracted. The frequency of immunisation within the recommended interval against pneumococcal infection was around 33% in both TN and UC practices.

Overall following spirometry for those with OLF/RLF, a new respiratory medication was prescribed to 45% of participants in UC practices and 11% of participants in TN practices, a significant difference (p <0.0001) (Table 6.23). The difference was also significant for those with AO who had data extraction, 54% in TN practices versus 12% in UC practices (p <0.0001).

There were no significant differences in the proportion of participants with OLF/RLF or AO whose respiratory medication was changed following spirometry (Table 6.23).

Table 6.22: Prescribed respiratory medications for OLF and RLF data extraction population by TN and UC spirometry model before and after spirometry

	TN practices n=226 (%)		*UC practices n=40 (%)*	
	Before	After	Before	After
Medication:				
SABA	42 (18.6)‡	47 (20.8) §§	18 (45.0)‡	21 (52.2) §§
Ipratropium	3 (1.3)*	1 (0.4)**	3 (7.5)*	3 (7.5)**
Tiotropium	9 (4.0)‡	10 (4.4) §§	8 (20.0)‡	13 (32.5) §§
LABA	4 (1.8)	4 (1.8)	0	0
ICS	17 (7.5)	17 (7.5)	3 (7.5)	1 (2.5)
ICS/LABA combination	12 (5.3)*	13 (5.8) §§	7 (17.5) *	12 (30.0) §§
Theophylline	2 (0.9)	1 (0.4)	0	2 (5.0)
Immunisation:				
Influenza	103 (45.6)	89 (39.4)¶	16 (40.0)	19 (47.5) ¶
Pneumococcal	64 (28.3)	76 (33.6) ¶¶	6 (15.0)	13 (32.5) ¶¶

SABA= Inhaled short-acting inhaled beta-2 agonist, LABA= Inhaled long-acting inhaled beta-2 agonist, ICS= Inhaled corticosteroid.

* $p<0.05$ TN v UC before spirometry, ** $p<0.05$ TN v UC after spirometry

† $p<0.01$ TN v UC before spirometry, †† $p<0.01$ TN v UC after spirometry,

‡ $p<0.001$ TN v UC before spirometry, ‡‡ $p<0.001$ TN v UC after spirometry

§ $p<0.0001$ TN v UC before spirometry, §§ $p<0.0001$ TN v UC after spirometry

¶ Based on data extracted before winter immunisation programme completed

¶¶ Five yearly vaccination recommended interval

Table 6.23: New and changed respiratory medication prescribing for participants with data extracted in TN and UC practices.

Prescription of inhaled respiratory medications	*TN practices*	*UC practices*
	Data extraction population with OLF/RLF	
	n=226 (%)	*n=40 (%)*
New medication	24 (10.6)*	18 (45.0)*
Medication changed	18 (8.0)	3 (7.5)
	Data extraction population with AO	
	n=110 (%)	*n=24 (%)*
New medication	13 (11.8)*	13 (54.2)*
Medication changed	15 (13.6)	2 (8.3)

* $p<0.0001$ for comparison between TN and UC

6.2.16.6.3 By doctor-recorded diagnosis of COPD

The participants with a doctor-recorded diagnosis of COPD were compared between practices with the TN or UC spirometry model for the use of inhaled tiotropium and corticosteroids. Among the participants with AO (Table 6.23), prior to spirometry, there was a significant difference in proportions being prescribed tiotropium and combination inhaled ICS/LABA that became even more marked following spirometry, when the proportions being prescribed either agent were 38% of participants in UC practices and 7% in TN practices (p <0.0001). Prior to spirometry, 7% of participants with AO were prescribed both prescribed tiotropium and combination inhaled ICS/LABA and following spirometry 24% were prescribed both agents.

As reported in section 6.2.13.5.2, a significantly greater proportion of participants with AO had a doctor-recorded diagnosis of chronic respiratory disease in UC practices than TN practices after spirometry. Among these participants, COPD was diagnosed in 42% (10/24) in UC practices and in 17% (19/110) in TN practices In UC practices, 70% were prescribed tiotropium and 70% were prescribed a combination inhaler (Table 6.24). In TN practices, 37% were prescribed tiotropium and 26% a combination inhaler. The numbers are small thus the differences in these results must be interpreted with caution.

Table 6.24: Prescription of inhaled corticosteroid/long-acting beta agonist combination inhalers and tiotropium for participants with AO and doctor-diagnosed COPD in TN and UC practices

	TN practices n=110 (%)		UC practices n=24 (%)	
Prescription of:	AO participants			
	Before	After	Before	After
ICS/LABA combination	7 (6.4)*	7 (6.4)††	5 (20.8)*	9 (37.5) ††
Tiotropium	7 (6.4)*	8 (7.3) ††	5 (20.8)*	9 (37.5) ††
	Doctor-diagnosed COPD participants			
Prescription of:	n=19 (%)		n=10 (%)	
ICS/LABA combination	3 (15.8)	5 (26.3)**	2 (20.0)	7 (70)**
Tiotropium	5 (26.3)	7 (36.8)	4 (40.0)	7 (70)

* $p<0.05$ TN v UC before spirometry, ** $p<0.05$ TN v UC after spirometry

†† $p< 0.0001$ TN v UC after spirometry

6.2.16.7 Repeat lung function testing

In TN practices, 10 (4.4%) participants had repeat spirometry. GPs repeated testing in 6 participants, of whom 2 participants had bronchodilator reversibility assessed and 4 participants were referred for testing in a lung function laboratory.
In UC practices significantly more participants, 9 (22.5%) had spirometry repeated ($p<0.001$). GPs repeated testing for 3 participants without bronchodilator reversibility and 6 participants were referred to a lung function laboratory.

6.2.16.8 Referral for other diagnostic or specialist services (Table 6.25).

Small numbers of participants were referred for chest radiology and pulmonary rehabilitation though there was no significant difference between TN and UC practices
Significantly more participants in UC practices were referred to a respiratory specialist after spirometry.

6.2.16.9 Recording of respiratory symptoms and physical activity after spirometry (Table 6.26)

The frequency with which respiratory symptoms or physical activity levels were recorded was affected by presence of a diagnosis of COPD and both were significantly more common in those with a diagnosis recorded ($p<0.0001$) with around 50% of those diagnosed with COPD having a recording of symptoms but less than 30% having activity levels recorded in both TN and UC practices.
Respiratory symptoms but not physical activity levels were less likely to be recorded for all participants in TN practices than UC practices ($p=0.02$). Activity levels were least frequently recorded with less than 10% of those with OLF or RLF having any record made in either TN or UC practices.
A significantly greater proportion of participants in UC practices (20%) had a record of respiratory exacerbations than in TN practices (7%) ($p<0.01$). In TN practices 20% of those with a diagnosis of COPD had a record of exacerbations but significantly fewer (5%) of those without a diagnosis ($p<0.01$).

Table 6.25: Referral for other respiratory services for participants with data extracted in TN and UC practices.

	TN practices n=226 (%)	*UC practices n=40 (%)*
Chest X-ray	7 (3.1)	3 (7.5)
Referral to respiratory specialist	6 (2.7)*	4 (10.0) *
Referral for pulmonary rehabilitation	2 (0.9)	1 (2.5)

(* p<0.01 for comparison between TN and UC participants)

Table 6.26: Recording of respiratory symptoms, physical activity and exacerbations following spirometry for OLF/RLF participants with data extracted in TN and UC practices.

		Symptoms	*Activity*	*Exacerbations*
		n (%)	*n (%)*	*n (%)*
TN practices	Diagnosis COPD (n=25)	13 (52.0)§§	7 (28.0) §§	5 (20.0) §
	No diagnosis COPD (n=201)	21 (10.4) §§	5 (2.5) §§	10 (5.0) §
	Total (n=226)	34 (15.0)*	12 (5.3)	15 (6.6)**
UC practices	Diagnosis COPD (n=16)	8 (50.0)	2 (12.5)	4 (25.0)
	No diagnosis COPD (n=24)	4 (16.7)	1 (4.2)	4 (16.7)
	Total (n=40)	12 (30.0)*	3 (7.5)	8 (20.0)**

§ p <0.01 diagnosis COPD v no diagnosis, §§ p <0.0001 diagnosis COPD v no diagnosis,

* p <0.05 TN practices v UC practices, ** p <0.01 TN practices v UC practices

6.2.16.10 Recording and accuracy of smoking status in practice records

The presence of a record of this important risk factor for many diseases was examined in the total target group population that had data extracted. In addition to data extraction carried out for participants in OLF and RLF spirometry categories (current smokers 108, ex-smokers 158), data were also extracted from the records of all current smokers in the NLF category (n=102). The sample of 368 participants included 315 participants in TN practices and 53 participants in UC practices.

Paper records and computer records were examined and the presence of any record, in either type of record, prior to spirometry was noted. The computer smoking status option is easily visible on the initial page of a patient computer record, whereas an entry in paper records was often be very difficult and time-consuming to locate meaning the GP would not immediately know if the patient's smoking status during a consultation. Therefore, if the only entry in a paper record pre-dated spirometry and the smoking status options box in the computer record had not been completed following spirometry, the participant was classified as "smoking status unknown" for the purpose of analysing these results.

Prior to spirometry, 32% of participants in TN practices and 30% of participants in UC practices had no record of their smoking status (Table 6.27). For current smokers only

When data extracted from practice records were compared only in current smokers, 36% had no record of smoking status pre-spirometry (Table 6.28). Before spirometry, the proportions of participants of current smokers who were recorded as such, was 56% in TN practices and 70% in UC practices, a non-significant difference (p =0.59).

As stated above, the completeness of recording of smoking status after spirometry was based on only the computer record entry (Table 6.29). In TN practices, the proportion of smokers with a correct record of their status as a current smoker was only 40%, lower than before spirometry. This was significantly lower than in UC practices in which the status of current smokers was correctly recorded for 89% of smokers (p<0.0001).

Table 6.27 Recording of smoking status before spirometry in TN and UC practices for participants in OLF/RLF categories and smokers with NLF with data extracted.

Smoking status recorded pre-spirometry	*Trained nurse n=315* (%)	*Usual care n=53* (%)	*All practices n=36* (%)
Not recorded	102 (32.4)	16 (30.2)	118 (32.1)
Current smoker	117 (37.1)	20 (37.7)	137 (37.2)
Ex-smoker	82 (25.1)	18 (32.1)	100 (26.1)
Non-smoker	17 (5.4)	0	17 (4.6)

Table 6.28: Recording of smoking status before spirometry for current smokers in OLF, RLF or NLF categories with data extracted in TN and UC practices.

Smoking status recorded pre-spirometry	*Trained nurse n=183* (%)	*Usual care n=27* (%)	*All practices n=210* (%)
Not recorded	68 (37.7)	6 (25.9)	74 (35.7)
Current smoker	102 (55.7)	19 (70.4)	122 (57.6)
Ex-smoker	11 (6.0)	1 (3.7)	12 (5.7)
Non-smoker	2 (1.1)	0	2 (1.0)

Table 6.29: Recording of smoking status after spirometry for current smokers in OLF, RLF or NLF categories with data extracted in TN and UC practices.

Smoking status recorded post-spirometry	*Trained nurse n=183* (%)	*Usual care n=27* (%)	*All practices n=210* (%)
Computer record: status unknown	107 (58.5)	3 (11.1)	111 (52.4)
Current smoker	74 (40.4)	24 (88.9)	97 (46.7)
Ex-smoker	2 (1.1)	0	2 (1.0)

6.2.16.11 Advice and assistance with smoking cessation given by GPs to smokers following spirometry

In both TN practices and UC practices the proportion of smokers recorded as having received counselling on smoking cessation following spirometry was low. In TN practices 19% of participants had such a record, compared to 26% of participants in UC practices, a non-significant difference (p=0.41).

There was no recorded assistance with smoking cessation for 89% of smokers in TN practices or for 96% in UC practices. In TN practices, 21 of smokers were given specific assistance with smoking cessation while in UC practices only 1 smoker received specific assistance (Table 5.30).

Table 6.30: Smoking cessation assistance recorded for participants in TN and UC practices

	TN practices n=183 (%)			*UC practices n=27 (%)*
Counselled on smoking cessation	35 (19.1)			8 (29.6)
Assistance with smoking cessation*:*	NLF	OLF	RLF	NLF/OLF/RLF
Any assistance	7	10	4	1
Nicotine replacement therapy	1	2	2	1
Bupropion	3	3	1	0
Smoking cessation clinic	1	2	0	0
Other e.g. hypnosis	2	3	1	0

6.3 Discussion

This study examined how spirometry testing could be increased in a real life general practice situation in Australia in the group of patients at risk of COPD, those over 35 years of age who had ever been regular smokers. The models for delivery of spirometry that were compared are feasible in primary care and both addressed some of the barriers previously identified in the preliminary study (Chapter 3). The impact of spirometry availability on clinical outcomes and especially on the recognition of COPD in practices was assessed.

6.3.1 Frequency of spirometry in the target group

The absolute number of tests performed in the target group of patients was much greater in practices offering testing with the Trained Nurse (TN) model of delivery than in practices offering testing with the Usual Care (UC) model of delivery. Similarly, there was a highly significant difference in the proportions of the eligible population that underwent spirometry between the two models of delivery in practices during six months.

Although a number of assumptions about practice attendance data were made in the calculation of these proportions, the large difference in absolute numbers corroborate the advantage for increasing testing when spirometry is delivered in a model of opportunistic testing by trained personnel, rather than being dependent on the usual practice of a general practitioner, even when trained and provided with a reliable and easy to use spirometer, and when paid a fee for this service.

The number of tests performed per week on patients in the target group was fewer than the pre-study estimations for both spirometry delivery models. In the TN model, calculations were based on the maximum number of tests that could be performed during the sessions (allowing 12 minutes per test) but this did not account for variation in practice sizes or the proportion of patients consulting who were not in the target group. The actual time spent on testing, excluding anything other than essential elements, was generally less than that allowed for in the calculation, but the time spent offering and explaining testing had not been adequately included. However, with trained nurses testing a median of six patients in the target group per week, there is still considerable capacity in this model to increase the numbers tested and thus the efficiency of this model. The estimated coverage by spirometry testing of around 25% for all patients in the target group, who were seen at least once during the six-month study period, could certainly be increased.

In the UC model, the pre-study estimate of 2.9 tests per week was based on the mean number of tests in all practices taking part in a previous study on the effect of training on the quality of spirometry in primary care in New Zealand (112). However, in that study only 14% of spirometry was performed for COPD; 22% was for investigation of symptoms and 43% was for asthma management. Interestingly, previous experience has been that practices which received training in spirometry actually performed fewer tests (1.5 tests per week) than those supplied with a spirometer without specific training in performance of testing (112), perhaps because of more discrimination about the indications and usefulness of the test.

In this study, the frequency of testing in the target group in UC practices (0.7 -1.5 tests/week) was similar to the frequency of use for COPD or investigation of symptoms in Eaton et al (112), and the frequency of overall use (1.5 – 2.3 tests/week) in my study was similar to the overall frequency reported by Eaton et al (112). The frequency of spirometry found in practices in the USA after a one-hour training session whose content was the very similar to that given in my study, increased from 0.5 test/week to 1 test/week (114).

GPs in UC practices indicated that most spirometry was actually performed by their practice nurses over the study period, and they stated clearly that the frequency of testing would depend on having a practice nurse to perform testing. The presence of a practice nurse was also found to be overwhelmingly the largest and most significant practice-related factor for the variation in utilisation of spirometry among well-trained GPs in practices equipped with electronic spirometers in Belgium (119). Overall, the authors of that study concluded that 17% of the variation in GPs spirometer utilisation was due to practice-related factors. Other practice-related factors such as the amount of delegation of medical tasks to practice assistants, having spirometry testing in more than one room, task differentiation among GPs and the use of protocols had much smaller effects. However, variable GP thresholds for initiation of testing and whether the GPs had attended spirometry training recently were found to be important practitioner-related factors on use of spirometry in normal clinical practice in that study(119). Support for the requirement of GPs to initiate testing in usual clinical practice in explaining variable spirometry use also emerged from my qualitative results. Despite the value GPs assign to having spirometric data on a patient, they may need a prompt to initiate a test, such as an algorithm or an automatically generated computer prompt.

The importance of recent spirometry training as a significant practitioner-related factor in spirometer use also found in other studies (114,119) was supported by results in my study. Poels et al found that being interested in research and having higher job satisfaction were significant factors in spirometry use, but they were still unable to explain 85% of the variance at GP level, and concluded that other unknown factors exist (119).

It was unclear to what extent the observation made by GPs, that a nurse performing spirometry is less threatening to patients, might affect initiating or performing spirometry by GPs. Although GPs in other studies have avoided raising topics that could cause distress (290) or a negative response in patients who smoke (250).

Incorporating regularly available spirometry sessions into routine clinical practice could reduce negative responses by patients to being “singled out” for spirometry and overcome the prejudice of GPs that this would occur.

6.3.2 Quality of spirometry performed

The proportions of spirometry tests meeting ATS standards for acceptability and reproducibility that were classified as good in TN practices (91%) and UC practices (63%) both exceeded the proportion with at least two reproducible exhalations (13.5%) found in the study of Eaton et al (112). However, spirometry performed in the trained nurse model of delivery was much more reliable in meeting the ATS standards and providing a result amenable to accurate interpretation. The proportion of tests of good quality was similar to the 72% achieved a sample of tests (n=74) in practices in the study of Kaminsky et al (114) in the USA.

The proportion of spirometry graded at the highest level (grade A) was lower in UC practices (38%) than TN practices (64%), which implies a technical superiority for the operators in the TN delivery model that is likely to be based on their much greater experience and more frequent performance of spirometry than operators in the UC delivery model, who included both GPs and practice nurses.

Feedback from doctors indicated that they personally found spirometry difficult to perform to high standards in an acceptable time period with infrequent use, despite having received training and this was confirmed in spirometry quality monitoring during the study. It seems clear that training needs to be supplemented by sufficient regular practical use to maintain standards and this may not be possible in an average doctor’s practice. The experience of GPs in this study corroborates the need to maintain competency through gaining and maintaining sufficient experience after initial training (and undergo refresher training) that is included in international guidelines on lung function testing (291)

6.3.3 Acceptability of spirometry to patients

A direct approach to patients by a nurse offering a spirometry test was acceptable to patients, which rather belies some GPs’ presuppositions, with only 8% of the population approached in practices refusing spirometry because they were not interested in knowing about their lung function. In addition few refused because they thought their lungs were OK (7%). No data were found in other studies on patients’ reasons for not agreeing to spirometry. Although the non-participation rate of 32%

was higher than found in other similar studies (108,110), this was explained by the high percentage of patients feeling too unwell to perform spirometry when presenting for a consultation in busy general practices. The lower refusal rates (2-3%) for opportunistic spirometry in the other studies was likely to be due to pre-selection of participants from amongst scheduled patients, whereas my study aimed to reflect the "real world" general practice and an opportunistic situation, without excluding or forewarning any patient in the target group. The refusal rate for opportunistic spirometry offered to the same target group population was not reported in a study of rural Canadian practices (292), although they compared characteristics of eligible patients that did not have spirometry. They reported that those not tested were older (mean difference 2 years) similar to the population of refusers in my study. There were 10% more males among refusers in my study but only 1% more in those not tested in Dales et al. However, refusers were more likely to be ex-smokers in my study and this was probably reflected in the non-tested population in Canadian practices that had a lower pack-year history (292). Those individuals in the target group for case finding who have already quit smoking may feel they are at lower risk of COPD, and may therefore be more likely to refuse spirometry when offered a test opportunistically.

6.3.4 Utility of the algorithm for classifying spirometry

The purpose of classifying spirometry with the algorithm was to select participants for data extraction follow up and to give feedback to smokers recruited for follow up. The criteria for OLF included, FER <85% predicted, to allow for the changes in FER which occur with age (43), or maximum expiratory flow rate at 25-75% of vital capacity ($FEF_{25-75\%}$) <55% predicted, as an indicator of small airways damage (41). Use of these criteria for airflow limitation identified more participants than use of the single criterion, ratio FEV1/FVC lower than 0.7, used in GOLD guidelines for the diagnosis of COPD (54), although in my study it was based on a pre-bronchodilator measurement.

GOLD guidelines have also proposed inclusion in the classification of stage 0, named the "at risk" stage, in which patients have symptoms of cough and sputum production but the ratio of FEV1/FVC is at least 0.7. In a study in Germany, among 1,434 patients referred to a respiratory specialist for diagnosis, 37% of those diagnosed with COPD were classified with stage 0. The presenting symptoms included exertional dyspnoea in 40%, cough in 85% and sputum in 50% (293). In my

study, data on participants' symptoms of cough or sputum production were not recorded, thus the proportion of participants in the target group in GOLD stage 0 cannot be established.

Of participants classified as OLF in my study, 43% of had a ratio of FEV1/FVC of 0.7 or greater, 74.3% of the whole target group population. A Canadian study of patients in the same target group as this study in rural general practices found that 82.6% had pre-bronchodilator FEV1/FVC >0.70 (292). Among the participants in my study with OLF but not AO, 75% had some degree of functional dyspnoea, 21% used inhaled respiratory medications and 10% reported a diagnosis of COPD. In those without AO in the Canadian study, there were similar rates, with 15% using inhaled respiratory medications and 23% reporting a respiratory diagnosis. Dales et al also recorded the presence of specific respiratory symptoms and found cough and phlegm in 20% of participants without AO (292). Functional dyspnoea was the only symptom measured in this study, present (at least to a mild degree) in 68% of those with NLF, 74% of those with OLF but without AO and 89% of those with OLF and AO.

Spirometry was not fully normal in those classified with stage 0 in the study of Kornman et al, with significantly lower FEV1 and $FEF_{25-75\%}$ compared to normal age-matched non-smokers (293). The mean $FEF_{25-75\%}$ in stage 0 in that study was 60% predicted compared to 46% predicted in my study in participants with OLF but FEV1/FVC ratio of 0.7 or greater.

Thus, use of the OLF criteria in this study identified 110 participants, 17.8% of the target group population undergoing spirometry. They had a substantial smoking exposure and 42% were still smokers. They had abnormalities on spirometry, that did not meet the classification criteria specified in guidelines (3,54), mainly impairment of small airways function. Even though they failed to meet these diagnostic criteria nearly a third reported a respiratory diagnosis, with 10% reporting a diagnosis of COPD. The same level of over-diagnosis of COPD was found in patients in Canadian practices (292) and represents the failure in primary care to base the diagnosis of COPD on spirometry.

There is evidence that stage 0 COPD is associated with increased mortality (294,295), and the association is stronger in the presence of any respiratory symptom (295). It is this group that is likely to progress to more overt COPD by conventional criteria. Thus, justification for diagnosing COPD stage 0 is to alert smokers to their susceptibility to lung damage and to counsel on smoking cessation strategies (293).

The use of $FEF_{25-75\%}$ or reduced FEV/FVC ratio in my study was deliberately chosen to define a population with OLF that included those with earlier, milder lung damage. Participants in the OLF group that would not have been identified by a reduced FEV1/FVC ratio alone had significantly lower self-rated lung damage than those with AO. They may be unaware of existing lung damage before spirometry but identifying and informing them of an obstructive abnormality on spirometry, demonstrates their risk from smoking and reinforces the need to quit (results on the effect of such feedback are analysed in chapter 7).

6.3.5 Spirometry for case finding in COPD

The opportunistic spirometry undertaken in the TN model of delivery did enable more patients without known respiratory disease to be tested. GPs confirmed they were aware of and valued this aspect of opportunistic testing in the discussions of their usual clinical practice. These patients had fewer symptoms and where airflow obstruction was present, it was more likely to be of mild severity, as discussed above. In contrast in UC practices, among patients having spirometry 62% already had doctor-recorded diagnosis of respiratory disease before testing. This frequency is the same as that found in the patients who were referred by GPs for testing in an open-access community spirometry service (296) and supports the finding in my study that fewer patients undergo spirometry when testing is based on a GP initiating a referral. Similarly, the lack of requirement for a referral from a GP for spirometry in TN practices may explain the high level of mild obstruction (41%) in participants with airflow obstruction detected in my study compared to only 4% in patients with COPD in a spirometry service for which access depended on GP referral (296).

Relatively few studies have actually examined practice records to assess how spirometry results are subsequently used in clinical consultations. Extraction of data from practice records is labour intensive and the reliability of results can be affected by poor or incomplete record keeping. All participating practices used computerised recording for consultations. Computerised records have been shown to compare favourably for completeness and accuracy to paper records (297). However, a study of GP computer records in four UK practices between 1982-1984 found disease recording rates were low, ranging from 72% for diabetes to 43% for myocardial infarction (298). A study on COPD diagnosis in a UK practice in 2004 found incomplete recording, the sensitivity of a search being 79%, and inaccuracy in recording with a positive predicted value for the code of 75% (299). All practices

participating in this study met Australian accreditation standards, including those for record keeping, practice services and administration (260). In spite of this, it is not possible to assess how accurately the data extracted reflects the clinical practice of GPs. Concordance between direct observation of patient visits and medical record review varies for different items of medical services, being generally higher for examination and lower for counselling including tobacco history and smoking cessation advice (300). Moderate concordance was found by Stange et al on the reason for the visit when it involved a visit for chronic disease, either routine or for an exacerbation (300). In a study in the Netherlands in 1989 with simulated patients, only 29% of items relating to the history of the patient's condition were actually recorded compared to 68% of items relating to medication and therapy for the conditions (301).

Data extracted in practices highlight the gap between having spirometric evidence of airflow obstruction available to doctors in primary care and actually increasing the diagnosis of COPD in the target group population. The rate of new doctor recorded diagnosis was low in both TN practice and UC practices, but the potential advantages of testing patients who would not otherwise have had spirometry was lost in TN practices without recognition and recording of a diagnosis. Three months following spirometry in participants with definite airflow obstruction (FEV1/FVC <0.7) who had data extracted from the practice records, 19% had a doctor-recorded diagnosis of COPD, 19% had a doctor-recorded diagnosis of asthma and 2% a doctor-recorded diagnosis of "chronic bronchitis", but the remaining 60% had no diagnosis recorded. This is striking in comparison to only 30% of the participants with definite airflow obstruction in UC practices that remained without a diagnosis when their records were examined (down from 38% prior to spirometry).

One explanation for the continuing gap in recognition and diagnosis of airflow obstruction between practices having the different spirometry delivery models may merely lie in lack of follow up of spirometry test results. Such a lack of follow up in TN practices, may explain the lower rate of repeat spirometry, fewer referrals for more complex lung function testing and fewer referrals to respiratory specialists for participants in comparison to UC practices.

One possible contributory factor to lack of recognition and possible lack of review of the spirometry results was the failure to return for a consultation, but only by a minority of participants. Doctors emphasised the need to include a specific follow up appointment after spirometry when evaluating their experience of the TN model of

spirometry delivery in focus groups. However, following reception of a test result in TN practices, it was still not universal for it to be discussed by doctors with the patient during a subsequent consultation, when the agenda was usually driven by the patient's presenting complaint. This preference for addressing the patient's agenda within the time limitation of a consultation has been found previously in relation to doctors discussing smoking cessation with their patients (250). The appropriate course of action upon diagnosis of COPD is promotion of smoking cessation (53) and doctors in this study may also have been using their judgement and knowledge of a patient in making the decision to communicate a diagnosis or not.

Failure to recognise spirometric abnormalities in those whose results were reviewed is also likely to have contributed to under-recording of new diagnoses of COPD in my study. This inaccurate interpretation of spirometry by GPs is supported by the misclassification of COPD in participants without airflow obstruction and the considerable inaccuracy in the interpretation of spirometry in the clinical scenarios discussed in focus groups with GPs. Other studies have confirmed that even after training most doctors were not confident about the criteria for diagnosis or classification (114,124).

A study in primary care in Canada found inaccurate interpretation of spirometry with 42% of patients with newly recognised airflow obstruction not actually meeting the specified spirometric criteria (302). The level of inaccurate interpretation occurred in that study despite the doctor being presented with the result immediately after seeing the patient, together with a reminder of the criteria for airflow obstruction. However, such a sequence of events does not mirror the usual flow of events in a spirometry referral service nor in the TN model investigated here, where there was no immediate relationship between spirometry testing and GP review of the result with patients. This need for further training in interpretation was emphasised in focus group discussions by all GPs. Automatic interpretation messages from in-built software may be supplied with the flow-volume curve and spirometry indices by the EasyOne spirometer used. This feature was not enabled during this study in order to investigate GPs' diagnostic practice after having undertaken a standard comprehensive training course and having experienced six months of applying the knowledge and skills gained. The advantage of having automatic interpretation was raised by GPs as a way to increase the clinical impact of spirometry and flagging the need for action. Although automatic interpretation by EasyOne spirometers has been found to agree with interpretation by a respiratory specialist in 92% of cases (284),

the 10% of tests that were classified as “borderline abnormal” by the specialist were excluded from the comparison. It is likely that these borderline abnormalities are precisely those most likely to be missed by doctors in primary care, again presumably in patients more mildly affected and potentially with most to gain. Mixed patterns and rare abnormalities were those missed by GPs trained in spirometry in a study in the Netherlands (124).

Follow up of spirometry undertaken through an open-access service in the UK (296) found a much higher rate of new diagnosis in practice records than in my study. A new diagnosis was recorded for 55% of participants with post-bronchodilator airflow obstruction (38% COPD and 16% asthma of COPD). Major differences from the TN model were that spirometry was performed only after GP referral and the result was supplied with an interpretative algorithm that included a likely diagnosis and assessment of severity. In my study, suggested by doctors the provision of such a report would assist them with interpretation of results. Doctors I interviewed in one practice also made the innovative suggestion that one of their members within the practice could “specialise” in interpretation. A model of GP specialist interpretation does appear feasible and was used in a study in Belgium (76), where although eight trained GPs performed spirometry testing, only two GPs in an academic department of general practice assessed all results. Newly detected COPD was found in 30% of previously un-diagnosed patients, based on this “expert” assessment of spirometry although there were no data on unassisted doctor-recorded diagnosis of COPD collected directly from practice records. The possibilities of developing additional expertise within the practice or having expert support for interpretation from specialists deserve further consideration (303).

One factor that seemed to have contributed to under-diagnosis of COPD when interpretation and recording a diagnosis relied on the GP, was the doctors’ doubts on the value of making a diagnosis of COPD or “giving the label” to a patient. The potential value of the label for promoting necessary behaviour change was emphasised by doctors in discussions, especially for those patients who were still smokers. Doctors did not value the diagnosis for epidemiological or disease prevalence purposes in their practices. This almost intentional under-diagnosis by doctors has not previously been considered, even in studies that used data extracted from practice records.

My study was carried out within two years following publication of Australian COPDX guidelines in 2003 (3) and it is possible that GPs’ practice had not yet

changed in response to the promotion by these guidelines of earlier recognition of COPD.

6.3.6 Effect of spirometry provision on clinical practice

The lack of any significant effects on medication prescribing after spirometry is unlikely to be due the limitation of practice record review in reflecting changes, since prescription and immunisation data in computer records are generally the most complete aspects (297,300,301).

I found that following spirometry in both TN and UC practices there were small increases in prescribing of specific respiratory medications. A much greater proportion of the target group undergoing spirometry in UC practices were prescribed a new respiratory medication (any sort) than in TN practices, although the proportions of participants with a recorded change of medication (including stopping a medication) were similar and less than 10% in both TN and UC practices. Less frequent recording of a new diagnosis in TN practices is likely to be the explanation for less frequent prescribing of a new medication, although some participants may have received a new medication despite not having received a formal diagnosis or having one recorded.

I was particularly interested in comparing prescribing between practices with TN and UC spirometry models for medications more recently introduced for COPD (287). Tiotropium is an anticholinergic agent that differs from the previously used ipratropium in its functional relative selectivity for muscarinic receptor subtypes resulting in a bronchodilating effect that lasts over 24-hours. It is known to be effective in reducing exacerbations and improving quality of life in COPD and was associated with a non-significant reduction in mortality from pulmonary causes compared with placebo or ipratropium in a meta-analysis (OR 0.50; 95% CI 0.19 to 1.29) (304). Fixed dose combination inhalers containing long-acting beta-agonists and inhaled corticosteroids in have been shown to give clinically meaningful improvements in COPD of at least moderate severity on quality of life, symptoms and exacerbations (305) and in a study of their use over three years a lower hazard ratio for death was found in the combination-therapy group as compared with the placebo group, 0.825 (95% confidence interval 0.681 to 1.002; p=0.052 after adjustment for interim analyses performed) (306). Thus use of these agents may not only reduce symptoms but also improve the prognosis when used in COPD.

There were increases in use of both tiotropium and fixed-dose combinations of inhaled corticosteroid and long-acting beta-2 agonists in participants in UC practices, though they were not statistically significant in the small sample. As already discussed, even when present most definite airflow obstruction (FEV1/FVC <0.7) was not recognised in TN practices and no diagnosis of COPD was recorded. This probably explains the lack of any increase in the use of these medications in TN practices.

In contrast to the difference in frequency of diagnosis of COPD in participants in TN practices and UC practices, the frequency of immunisation against influenza or pneumococcal infections was the same in both models, probably reflecting routine clinical practice in the age group of study participants.

Evidence-based clinical practice guidelines for doctors for promoting smoking cessation are based on the 5-As: Ask, Assess, Advise, Assist and Arrange (140). These guidelines recognise the need to elicit smoking status from patients in general practice and to maintain accurate and easily accessible records of smoking status (307). It is recognised that there may be incomplete recording of all activities undertaken in a consultation especially advice of behavioural change such as smoking cessation (300,301,308). Thus the low frequency of advice by GPs to participating smokers recorded following spirometry, and found in both TN and UC practices, may be an underestimate, as GPs may not always make a formal record of a brief reminder to stop smoking. However reviewing practice records enabled an objective assessment to be made of the accuracy of records with respect to participants' smoking status. The proportion of those undergoing spirometry in TN practices that lacked documented smoking status in their records three months after testing (59%) was the same as that found in an audit of medical records of 72 general practitioners in Queensland (309) but higher than in a UK study of patients coded with COPD in a UK practice (299). The practice studied in the UK was described as being relatively advanced in its use of information technology and it may differ from the practices in the study reported in this thesis.

An important theme from discussions with doctors was the major benefit of our spirometry programmes in being prompted to update records of smoking status for those tested. However, examination of the records did not provide evidence that this had occurred for the majority of participants in TN practices. Thus many opportunities for effective intervention following spirometry were missed, as there is

evidence that the rate of detection of patients' smoking status by GPs has a potentially greater effect on quit rates than increasing intervention levels (310). The incomplete recording of smoking status found after spirometry is inconsistent with stated intentions of doctors when using the scenarios, that they would always use a spirometry test as an entry to promoting smoking cessation. This may be another consequence of the lack of specific flagged follow up of opportunistic spirometry in practices that used the TN spirometry delivery model. In my study a much lower proportion of those undergoing spirometry had smoking cessation advice documented within three months of testing (19% in TN practices, 26% in UC practices) than in a UK study in which 76% of those GPs referred for open-access spirometry had documented advice and/or assistance (296) but of similar magnitude to the 29% of consultations with counselling observed in Australian general practice in 1992 (308). Although there may be lack of documentation of brief messages by doctors, specific interventions are more likely to be documented and their use in this study was also low.

6.3.7 Constraints of spirometry delivery models

The overall assessment by GPs of the feasibility of the TN model of spirometry delivery from qualitative evaluation was positive. Some potentially negative aspects could be overcome by improving practice systems e.g. implementing a protocol for flagging the test result and organising automatic recall of patients for follow up. Ensuring complete follow up would increase GPs workload however and this was already felt by all doctors to be too high. The finding of no increase in consultation rates from the follow up of practice records in the three months after opportunistic spirometry may reflect incomplete follow up in TN practices. However, no increase was found in UC practices either.

The time required to perform spirometry by the trained nurses was reasonable low, at around five minutes and similar to that in other studies of spirometry screening (108,111). From qualitative findings the time for spirometry appeared to be much higher in UC practices using a practice nurse, perhaps because testing was less frequently performed. It is possible that the time also included more discussion of the result or advice on health promotion in patients whose total care was the responsibility of the practice.

Although uptake of opportunistic testing in TN practices was high during the study, without better government funding for spirometry, doctors in these practices felt it

would not be financially viable to continue to offer testing. The fact that GPs in UC practices shared these reservations greatly diminishes the likelihood that GPs will use spirometry for case finding in COPD under the current funding system. In my study, GPs were paid for spirometry without administration of a bronchodilator and repeat testing, which differs from the circumstances under which testing is currently rebated under the Australian Government Medicare Benefits Schedule (311).

6.3.8 Cost effectiveness

Consideration of the value of spirometry in primary care and choice of the most effective model for delivery requires a full cost-benefit analysis (312). However, data available on costs of previously published models spirometry are very limited and incomplete (108,296,302). The costs of a screening and two-year follow up monitoring programme in ten practices in the Netherlands have been reported (121). The costs of the initial screening alone (excluding monitoring costs) for 1,155 subjects were US$22,668. Initially, 54 cases of undiagnosed COPD or asthma were recognised, a cost per case of US$420. That screening programme did not rely on participants' GPs to make a diagnosis and the cost is comparable to the cost of AUS$558 in this study, if all cases detected by opportunistic spirometry in TN practices were recognised. However in my study, the cost per actual case diagnosed was considerably more expensive if one took into account the practical reality that the data on airflow obstruction were usually ignored in most subsequent GP consultations.

Calculation of the costs of spirometry in both models in this study were based only on the direct costs of equipment, calibration checks and salary costs of performing testing by trained nurses. They did not take into account other practice-borne costs in UC practices. Nor did they include all the direct costs, such as for follow up, or any indirect costs, such as work loss or travelling, that would be essential for a full economic evaluation of screening spirometry (312).

However, long-term cost effectiveness of spirometry as a screening tool for COPD also depends on reducing costs from lost productivity through better management and reduced progression of the disease resulting from successful smoking cessation (313). New diagnoses of COPD were often accompanied by prescription of new medications that are more expensive than older bronchodilators, but more effective especially in reducing exacerbations (287).

Opportunistic testing was thought by GPs to improve identification of smoking status in order to initiate discussion on smoking cessation. False reassurance in smokers with normal lung function is a potential negative health effect of screening that should be evaluated in a full cost-benefit analysis (312). The effect of normal and obstructive spirometry results on smoking cessation are reported in Chapter 7.

Chapter 7
Effect of spirometry on smoking cessation and motivation for quitting

7.1 Rationale

7.1.1 Spirometry for case finding in COPD

Since the results of early longitudinal studies of lung function changes in smokers, physicians have presumed that measuring lung function and demonstrating the damage caused by smoking would persuade smokers to stop (16). Furthermore, smoking cessation is the only intervention accepted as effective in slowing the deterioration of lung function (135). As the overall beneficial effect is greatest the sooner cessation is achieved (4) early identification of those with obstructive airway damage is required so that efforts to promote smoking cessation can be focused on this group. Reliance on presentation with symptoms to identify these smokers will miss many individuals who have airflow obstruction, of whom between 40-80% are thought to be undiagnosed in the community (53).

A systematic review conducted for the US Department of Health in 2005 concluded that the value of case finding in COPD depended on knowing that spirometry improves smoking cessation rates (53), but there is no conclusive evidence from the limited randomised control studies that have been done that undertaking spirometry improves cessation rates (53,314).

Differences in study design and the use of co-interventions prevented pooling of data from seven randomised studies included in a systematic review (314). Only one study examined the independent effect of spirometry and this did not find a statistically significant increase in the rate of smoking cessation for spirometry alone (189). Further properly conducted randomised control trials have been recommended in the report to the US Department of Health to provide evidence of the effect of spirometry on smoking cessation after one year (53) but the likely number of participants required would make such a study difficult to perform in primary care.

There is some evidence from cohort studies in smokers for increased cessation rates in those shown to have obstructive lung function compared to normal lung function (192,193). However, in these studies smokers had to respond to an invitation advertised in the community to attend for spirometry testing conducted at a specialist centre. It is therefore possible that this self-selection and need for action meant those

included were more motivated to quit than “run of the mill” smokers in the general community (315).

7.1.2 Effect of abnormal and normal spirometry results on motivation to quit

As already stated, there is a general prejudice that demonstration of airflow limitation due to smoking will increase motivation to stop smoking (16). However, an important barrier to increasing the use of spirometry in primary care in COPD, identified in the preliminary study reported in Chapter 3, was doctors’ belief that smokers would be less likely to consider stopping smoking, and less likely to take steps to achieve smoking cessation, if their spirometry results were normal. Instead of being encouraged to stop smoking, which was thought to be the case for abnormal spirometry, a normal result might be seen as legitimising continued smoking. Thus, investigation of the motivational effect of spirometry testing in primary care was the primary question that this study was designed to address, using the “stages of change” model as a surrogate for smoking cessation. Sustained smoking cessation was investigated as a secondary outcome but recognising that the study probably would not have sufficient numbers to avoid a Type II error, i.e. lack of power.

7.2 Study design and recruitment

A longitudinal cohort of smokers was recruited during the intervention study that compared two practice-based models of spirometry provision in eight general practices in Tasmania. A full description of the methods used is given in Chapter 4, but the subjects recruited for the current investigation were restricted to the trained nurse model in the comparison.

7.2.1 Participant recruitment

During the period from November 2004 to December 2005 any smoker who underwent opportunistic spirometry testing performed by a trained nurse (TN) during a visit to a participating practice, was invited to participate in a follow-up study on smoking cessation. The inclusion criterion was classification of spirometry by the trained nurse according to the study algorithm, into either obstructive lung function (OLF) or normal lung function (NLF) categories (see methods, Chapter 4.10.3). Participants classified with restrictive lung function (RLF) were excluded from the study (see methods, Chapter 4.11.1 5).

7.2.2 Variation in practice recruitment and follow up

Trained nurses performed spirometry opportunistically during twelve months on 955 participants in the target group of smokers or ex-smokers aged over 35. Participants were classified on spirometry as follows: 545 (57.1%) with NLF, 354 (37.1%) participants with OLF and 55 (5.8%) participants with RLF (one poor quality result was not classified). In the NLF group, 195 (35.8%) participants were current smokers compared to 140 (39.6%) participants in the OLF group and it was these individuals who formed the group for study in this follow up investigation. Consent for follow-up with a questionnaire after three months was received from 328 (97.9%) participants, 193 with NLF and 135 with OLF with only 7 (2.1%) participants refusing.

The distribution of participants recruited varied across participating practices (Table 8.1). This generally reflected the number of opportunistic spirometry tests performed during the TN period as reported in chapter 6 (Table 6.2). Follow up after three months was carried out using questionnaires, the outcomes being assessed by self-report (see methods Chapter 4.11.1.8.2). The questionnaire was mailed, with a pre-paid reply envelope, to participants at the address recorded at the time of spirometry. If no reply was received, participants were contacted by telephone and the follow-up questionnaire administered by the trained nurse. At least two attempts to make contact by telephone were made, after which a reminder with another questionnaire was mailed to the participant's address. Overall, only 31 (9.5%) participants failed to complete the follow-up questionnaire, i.e. a response rate of 90.5%. These non-responding participants were included in analysis of smoking cessation rates and treated as continuing smokers. They were excluded from analyses of stage shift.

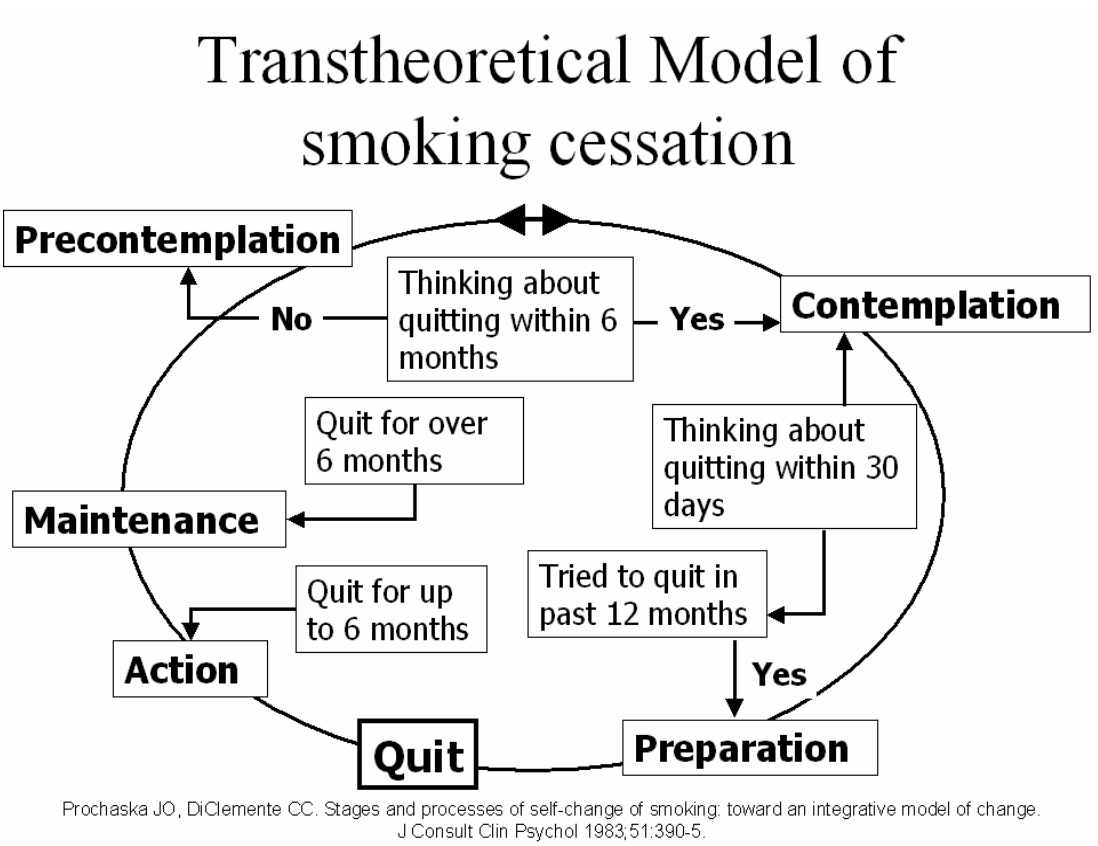
7.2.3 Trained nurse smoking cessation intervention

Standard brief advice on the importance of stopping smoking was given to every smoker who had opportunistic spirometry (see methods, Chapter 4.11.1.7). Participants with OLF were given feedback informing them that there was evidence of damage to the airways related to smoking and participants with NLF were informed that there was no evidence of damage to the airways. If further explanation or advice on smoking cessation was required by participants with NLF, follow up with a GP was suggested. Participants in the OLF group were asked to make an appointment to see a GP to discuss their result and if they wished, to ask for advice on smoking cessation.

Table 7.1: Participant recruitment and three-month follow-up by practice

	Number of participants from individual practice (% Of participants in an individual practice in the whole cohort)								
	1	*2*	*3*	*4*	*5*	*6*	*7*	*8*	*All*
Enrolment:									
Eligible	67 (20)	47 (14)	59 (18)	29 (9)	62 (19)	26 (8)	38 (11)	7 (2)	335
Refused	1	1	1	0	0	2	2	0	7
Follow up:									
Completed	59 (20)	41 (14)	53 (18)	26 (9)	59 (20)	22 (7)	31 (10)	6 (2)	297
Lost	7 (23)	5 (16)	5 (16)	3 (10)	3 (10)	2 (6)	5 (16)	1 (3)	31

Figure 7.1: A diagrammatic representation of the five stages in the Transtheoretical Model of smoking cessation.



7.2.4 Outcomes at three month follow up

The primary outcome of interest was change in intention to quit smoking after feedback on spirometry from the Transtheoretical Model of smoking cessation (See below 7.2.5). Secondary outcomes were sustained smoking cessation prevalence and attempts to quit smoking.

7.2.4.1 Analysis of stage shift in the Transtheoretical Model

The Transtheoretical Model (TTM) of smoking cessation (161) was used to determine participants' stages at baseline and follow up. The five stages in the model and their criteria based on an individual's intention to stop smoking are shown diagrammatically in Figure 7.1. The stage shift for individual subjects at three month follow up was designated as forward, backward or unchanged. If the direction of the stage shift was towards quitting (action) a forward or positive stage shift was designated and if the direction of stage shift was towards precontemplation, backward or negative stage shift was designated. The proportions of participants who had forward stage shift, backward stage shift or no change in stage were compared between the NLF and OLF feedback groups using cross-tabulation tables.

The hypothesis underlying this study was that increased motivation to quit smoking and increased smoking cessation would result from giving feedback that lung function testing showed damage caused by smoking compared to feedback that there was no evidence of such damage.

The effect of spirometry feedback category on the occurrence of forward stage shift, backward shift or no change in stage for intention to quit smoking was analysed using multinomial logistic regression, the appropriate method where the outcome variable is discrete but non-binary. There are three categories for which predictions need to be made. When the outcome category "no stage shift" was designated as the reference category the model computed two binary logistic regression equations using the categories "forward shift" and "backward shift" compared to the reference category.

7.2.4.2 Analysis of smoking cessation and attempts to quit

At three month follow up the number of periods of abstinence from smoking lasting at least 24 hours was recorded for each participant. Complete abstinence from smoking for at least the past seven days was recorded (see methods, chapter 4.10.9). For the purposes of analysis, participants who had not been successfully followed up

were assumed to be continuing smokers and not to have made an attempt to quit smoking. The proportions of participants who reported sustained quitting or who had made a quit attempt were compared between the NLF and OLF feedback groups using cross-tabulation tables.

A multiple logistic regression model that describes the relationship between several predictor variables and a binary outcome, achieving smoking cessation or making an attempt to quit smoking, was used to evaluate the importance of other predictor variables known or postulated to have effects on smoking cessation.

7.2.4.3 Outcome analysis at individual level

Although randomisation in the study comparing spirometry delivery models had been made at the practice level, follow up data on smokers were analysed at the individual level according to feedback on spirometry testing. Regression analysis was performed without controlling for correlated responses within practices. Justification for this was based on the design of the study under which all smokers in every practice received the same brief advice from a trained nurse regarding smoking cessation at the time of spirometry. Additional justification was obtained following analysis of data at follow up. Thus quit rates did not differ significantly and were similar between practices and practice records showed that proportions of participants with recorded advice or assistance on smoking cessation were low and again were similar across practices.

7.3 Cohort of current smokers

7.3.1 Baseline demographics (Table 7.2)

The mean age of participants in the cohort was 49.8 (SD10.3) years. Overall, for participants in the cohort 44.5% were male, 55.6% were living with a partner, 36.3 % had attained an educational qualification after grade 12 (trade/apprenticeship, certificate/diploma, university degree), 25.8% were not breathless or symptomatic with strenuous exercise, 25.2% reported a doctor-diagnosed respiratory illness and 17.2% reported using inhaled medication. Participants with OLF were significantly older (with a difference in mean age of 8.7 years) than participants with NLF, but the proportions in each group were similar for gender, whether living with a partner or living alone, and whether an educational qualification post-grade 12 was obtained. Participants with OLF were significantly more likely to have dyspnoea with exertion

(81.3% versus 69.3%), to report a respiratory diagnosis (37.7% versus 16.3% difference in proportions) or to report using an inhaled medication (26.1% versus 11.0%).

Among 135 participants in with OLF, when classified on the basis of FEV1 % predicted, 74 (55%) participants had mild obstruction, 54 (40%) participants had moderate obstruction, 6 (5%) participants had severe obstruction and one participant had very severe obstruction using GOLD criteria (10). However, for the purposes of this study, feedback on spirometry was regarded simply as dichotomous i.e. damage to airways from smoking, or not.

Table 7.2: Baseline characteristics of smokers by spirometry feedback groups- obstructive lung function (OLF) or normal lung function (NLF)

		NLF (n=193)	*OLF (n=135)*	*Total (n=328)*	*p value*
Age†		46.2 (8.1)	54.9(11.0)	49.8 (10.3)	<0.0001
Male (%)		87 (45.1)	59 (43.7)	146 (44.5)	0.81
Education (%)	Grade 1-6	4 (2.1)	6 (4.5)	10 (3.1)	0.12
	Grade 7-9	28 (14.7)	32 (23.9)	60 (18.5)	
	Grade 10-11	67 (35.1)	44 (32.8)	111 (34.2)	
	Grade 12	16 (8.4)	10 (7.5)	26 (8.0)	
	Trade / diploma	63 (33.0)	36 (26.8)	99 (30.5)	
	University degree	13 (6.8)	6 (4.5)	19 (5.8)	
Living with partner (%)		103 (54.5)	75 (57.3)	178 (55.6)	0.88
No exertion dyspnoea (%)		59 (30.7)	25 (18.7)	84 (25.8)	
Functional dyspnoea (MRC grades) (%)	Grade 1	31 (16.1)	24 (17.9)	55 (16.9)	0.02
	Grade 2	68 (35.4)	46 (34.3)	114 (35.0)	
	Grade 3	16 (8.3)	11 (8.2)	27 (8.3)	
	Grade 4	18 (9.4)	28 (20.9)	46 (14.1)	
Respiratory diagnosis* (%)		30 (16.3)	49 (37.7)	79 (25.2)	<0.0001
Inhaled medication use* (%)		21 (11.0)	35 (26.1)	56 (17.2)	<0.0001
FEV1 % predicted†		104.4 (12.7)	78.5 (17.2)	93.8 (19.5)	<0.0001
FVC % predicted†		105.6 (13.2)	93.7 (16.7)	100.7 (15.9)	<0.0001
FEV1/FVC†		0.80 (0.05)	0.67 (0.09)	0.75 (0.09)	<0.0001
MEF25-75% % predicted†		79.4 (21.0)	36.5 (13.0)	61.7 (27.9)	<0.0001
PEF % predicted†		109 (21)	82 (22)	98 (25)	<0.0001

(* reported by participant, † mean and SD, ‡ median and IQR)

7.3.2 Baseline smoking behaviour and health beliefs

7.3.2.1 Smoking history, nicotine addiction

Participants with OLF had significantly greater smoking exposure (38.6 versus 27.4 pack-years). However, the mean age of starting smoking was similar and there was no significant difference in the level of nicotine addiction between those in the NLF and OLF feedback groups (as measured by the heaviness of smoking index).

7.3.2.1 Stages of change

The distribution into stages of change in the Transtheoretical Model of smoking cessation before spirometry was very similar. Overall, 44% of smokers recruited were in precontemplation, 39% in contemplation and 17% in preparation (Table 7.3).

7.3.2.2 Self-efficacy and social support for quitting

Self-efficacy i.e. ability to achieve smoking cessation was assessed following spirometry feedback through response to the question "How confident are you that you could stop smoking completely if you decided to"? Overall 26.9% of participants had no confidence in their in ability to quit smoking, and 16% were very confident (Figure 7.2). The distribution of proportions did not differ by feedback group. In response to the question "How much do your family or friends want you to stop smoking", among all participants, 41% felt their family or close friends very much wanted them to quit smoking while 16% did not feel their family and friends wanted them to quit (Figure 7.3). There was no significant difference in distribution of response categories between feedback groups for such "social" support for quitting after receiving feedback on spirometry (Table 7.3).

7.3.2.3 Distribution of scores for perceived health and benefits of smoking cessation

Self-assessments of general health, lung damage and the benefits of quitting were made prior to spirometry using visual analogue scales (0-100). Scores were non-normally distributed and thus three bands were created to reflect the distribution of each variable across participants' scores. For self-rated general health and lung damage, a band lower than average (0-49) and two bands higher than average (50-69 and 70-100) were created. A majority of participants assessed the benefits of quitting smoking with a score of 100. Thus, the three groups were created with scores 0-80, 81-99 and scores of 100. The distribution of bands for these variables did not differ by spirometry feedback group as shown in table 7.3.

Table 7.3 Baseline smoking behaviour and health beliefs of participants by spirometry feedback group- obstructive lung function (OLF) or normal lung function (NLF)

		NLF (n=193)	*OLF (n=135)*	*Total (n=328)*	*p value*
Age start smoking[†]		17.1 (5.0)	17.0 (4.6)	17.1 (4.8)	0.81
Cigarettes/day[†]		19.0 (9.7)	20.3 (10.1)	19.5 (9.9)	0.30
Smoking exposure [1†]		27.4 (16.3)	38.6 (24.2)	31.8 (20.5)	<0.0001
HSI[2 †]		2.9 (1.5)	3.1 (1.5)	3.0 (1.6)	0.32
Stage of change:					
Precontemplation (%)		84 (44.2)	58 (43.6)	142 (44.0)	0.99
Contemplation (%)		74 (38.9)	53 (39.8)	127 (39.3)	
Preparation (%)		32 (16.8)	22 (16.5)	54 (16.5)	
Quit attempt in <12 months (%)		108 (56.0)	63 (46.7)	171 (52.1)	0.10
Self-rated general health[3]	0-49	51 (28.6)	39 (30.0)	90 (28.1)	0.82
	50-69	77 (40.5)	51 (39.2)	128 (40.0)	
	70-100	62 (32.6)	40 (30.8)	102 (31.9)	
Self-rated lung damage[3]	0-49	42 (22.0)	27 (20.5)	69 (21.4)	0.74
	50-69	56 (29.3)	35 (26.5)	91 (28.2)	
	70-100	93 (48.7)	70 (53.0)	163 (50.5)	
Self-rated quit benefits[3]	0-80	43 (22.5)	38 (28.6)	81 (25.5)	0.35
	81-99	52 (27.2)	29 (21.8)	81 (25.0)	
	100	96(50.3)	66 (49.6)	162 (50.0)	
Self-efficacy for quitting[4] (%)	None	48 (25.3)	39 (29.1)	87 (26.9)	0.83
	A bit	60 (31.6)	37 (27.6)	97 (29.9)	
	Quite	52 (27.4)	36 (26.9)	88 (27.2)	
	Very	30 (15.8)	22 (16.4)	52 (16.0)	
Support from significant others for quitting[4] (%)	Not at all	27 (14.3)	25 (18.5)	52 (16.0)	0.71
	A little	35 (18.5)	23 (17.0)	58 (17.9)	
	Quite a lot	50 (26.5)	31 (23.0)	81 (25.0)	
	Very much	77 (40.7)	56 41.5)	133 (41.0)	

([†] Mean and SD, [‡] median and IQR, [1] pack years, [2] heaviness of smoking index 0-6, [3] visual analogue score 0-100, [4] n=324)

Figure 7.2: Baseline self-efficacy for smoking cessation in participants by spirometry feedback group-obstructive lung function (OLF) or normal lung function (NLF)

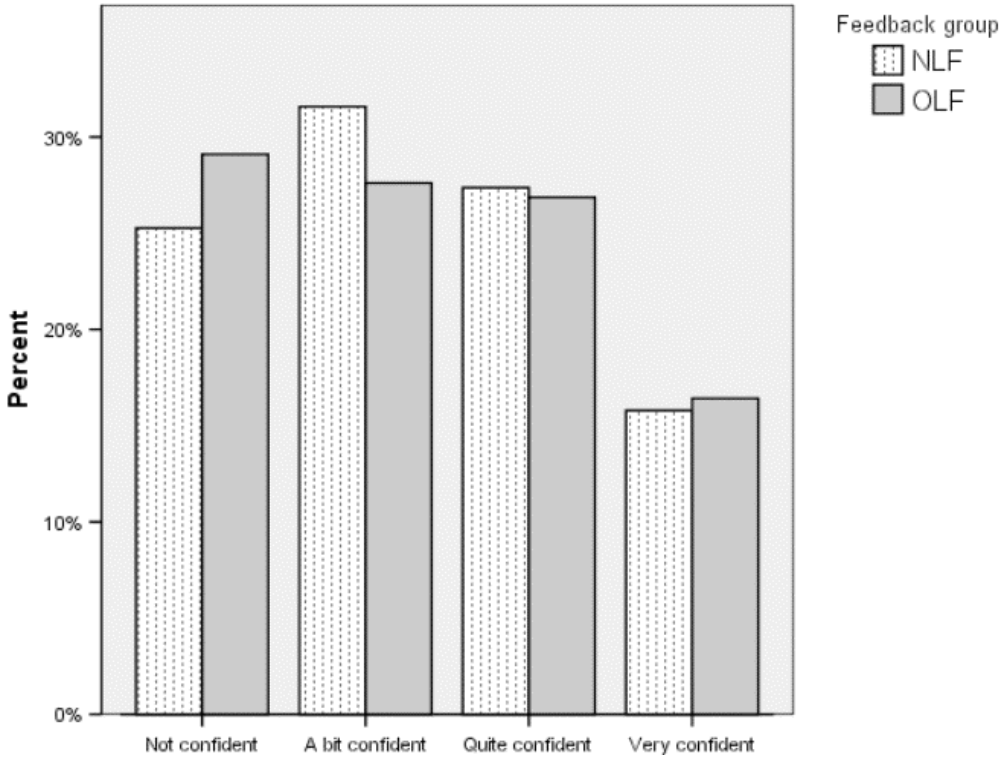
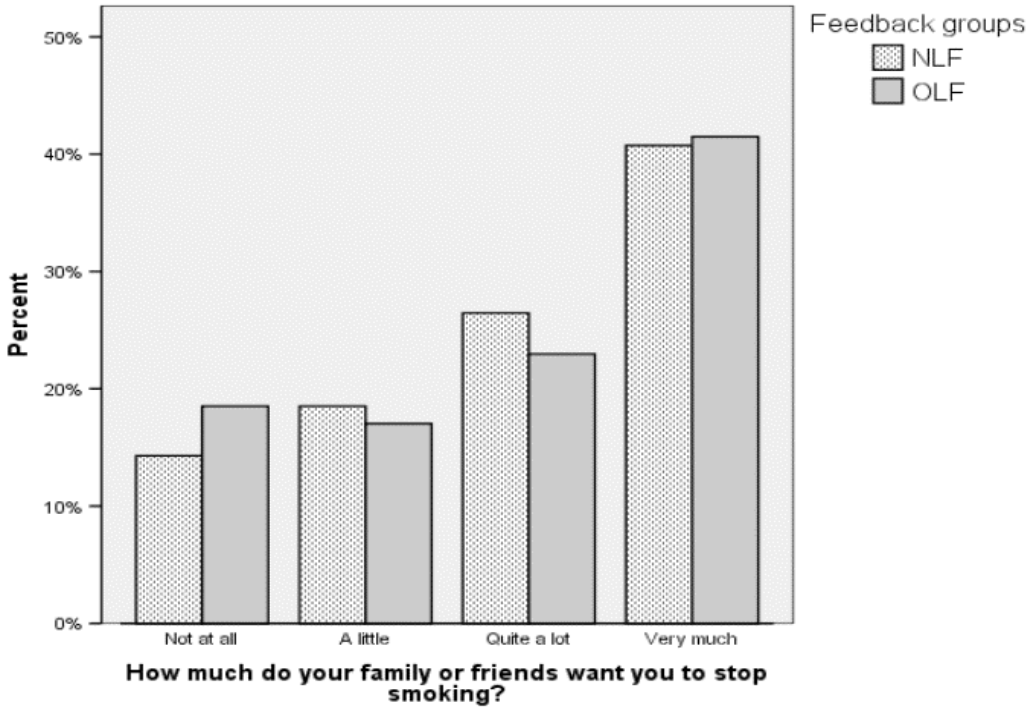


Figure 7.3: Baseline social support for smoking cessation by significant others in participants by spirometry feedback group-obstructive lung function (OLF) or normal lung function (NLF)



7.3.2.3 Relationships between perceived health, benefits of smoking cessation and other variables

Spearman's rank correlation was used to investigate relationships between attitudes to health and smoking and other variables. There was no significant difference between the NLF and OLF feedback groups in the scores for self- rated general health (Mann-Whitney test p=0.46). The median scores for NLF group participants (57, IQR 23) and OLF group participants (50, IQR 27), indicated assessment at about the community average for both. Interestingly, there was a weak positive correlation between self-rated general health scores and FEV1 percentage predicted (r_s 0.12, p<0.05) (Table 7.4).

However, perhaps paradoxically, there was no significant difference in scores for self-rating of lung damage due to smoking between the NLF feedback group (median scores 69, IQR 36) and OLF feedback group (median 70, IQR 44) (Mann-Whitney test, p =0.39). There was very strong belief in the benefits of quitting smoking, with median self-rated scores high in both groups, 100 (IQR 15) for NLF participants and (100 IQR 20) for OLF participants (Mann-Whitney test, p =0.65).

Self-rated scores for lung damage and the benefits of quitting were positively correlated (r_s 0.27, p<0.01), i.e. perhaps appropriately those who perceived the damage to their lungs from smoking as greater thought there was most to gain from quitting. Although statistically there was a very weak negative correlation between the perceived benefits of quitting and number of pack-years of smoking (r_s 10.12, p<0.05), the scatter plot indicated a very large number of smokers rated the benefits of quitting at 100% over a wide range of values for pack-years of smoking (Figure 7.4).

However, self-rated scores for lung damage and general health were negatively correlated (r_s –0.24, p<0.01) as smokers who perceived that they had greater damage to their lungs from smoking also perceived their general health as worse (Table 7.4).

Scores for self-rated health and the benefits of quitting varied with initial stage in the Transtheoretical Model, with general health assessment being worse (p=0.01) and the benefits of quitting being rated higher (p<0.0001) by smokers in the preparation stage (Table 7.5). Paradoxically more smokers in the preparation stage (42%, n=22) than in precontemplation (22%m n=32) were in the lowest tertile for general health rating (0-49/100). However, more smokers in the preparation stage (67%, n=36) than in precontemplation (39%, n=56) gave the highest possible rating of 100/100 for the benefits of quitting.

Table 7.4: Correlations between participants' self-rated scores for health, lung damage and benefits of quitting and pack-years of smoking

(Spearman's rank order correlation. * p <0.01, ‡ p <0.05)

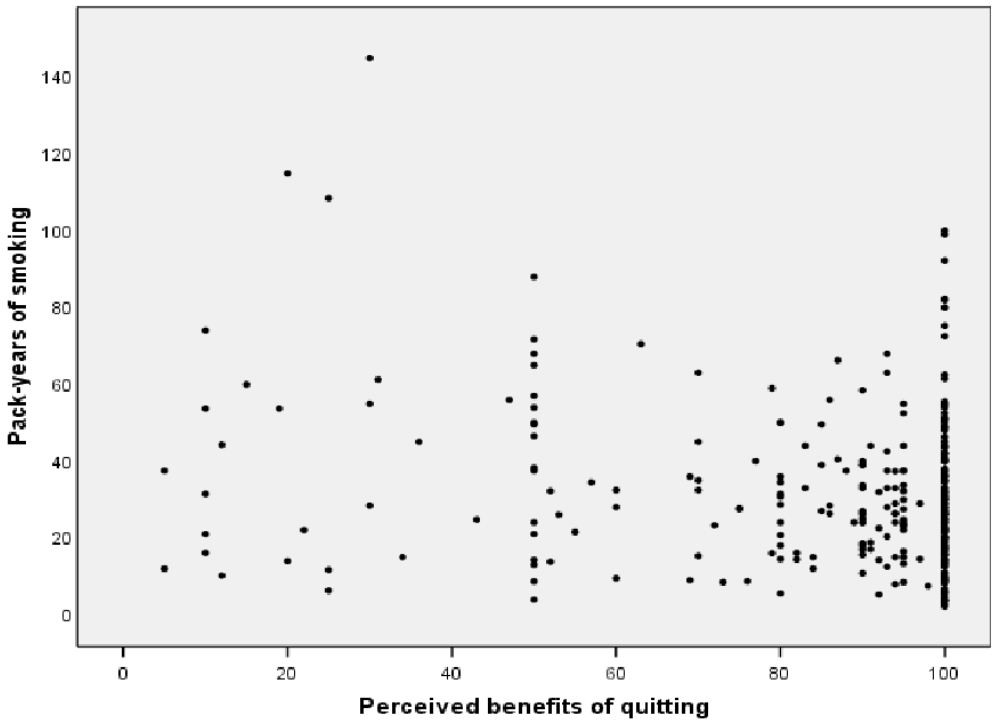
	General health	*Lung damage*	*Quit benefit*	*Pack-years*
General health	1	-0.24*	-0.51	-0.06
Lung damage	-0.24*	1	0.27*	0.09
Quit benefit	-0.51	0.7	1	-0.12‡
Pack-years	-0.06	0.09	-0.12‡	1

Table 7.5: Self-rated scores for health, lung damage and the benefits of quitting by baseline stage of change

	Precontemplation	*Contemplation*	*Preparation*
General health† *	58.3 (20.1)	57.7 (22.5)	47.4 (23.8)
Lung damage†	63.7 (28.2)	68.0 (23.6)	72.7 (24.1)
Quit benefit† ***	77.5 (28.9)	91.6 (15.8)	94.2 (11.9)

(† Mean and SD of visual analogue scores, * p< 0.05 ***p< 0.0001 using Kruskal-Wallis test)

Figure 7.4: Correlation between pack-years smoked and the perceived benefits of quitting



7.4 Results at three month follow up

Results at three month follow up are presented here in a number of domains given here the following order: follow up consultation with a GP; shift in stage of change; sustained smoking cessation; quit attempts; cigarette consumption; advice and assistance from GP with smoking cessation.

7.4.1 Consultation for follow up of spirometry with general practitioner

The proportion of participants who had at least one consultation with a GP following spirometry was extracted from GP records for 175 (53.4%) of the cohort, 89 in the NLF group and 86 in the OLF group. Although all of these participants were recruited during the first six-month period there is no reason to expect that the behaviour of participants recruited in the second period would differ with respect to the likelihood of consulting a GP. Among participants whose records were examined,

there was no significant difference in the proportions that had a consultation during the three months following spirometry by outcome of the test; 82.0% NLF participants and 87.2% OLF participants (p=0.34).

7.4.2 Stage shift in Transtheoretical Model of smoking cessation

Data on participants' baseline stage in the Transtheoretical Model were available for the whole cohort (n=328) but stage at three months following spirometry was only available for 297 (90.6%) participants owing to unsuccessful follow up. Participants for whom follow up was not successful were necessarily excluded from the analysis of stage shift.

As reported in sections 7.3.2 there was no difference in distribution of stages between the NLF and OLF feedback groups at baseline. At three month follow up, although a greater proportion of the OLF group was in preparation than the NLF group and 7.2% of the OLF group were in the action stage compared to 4.7% in the NLF group, the differences in distribution of stages between the NLF and OLF feedback groups were not significant (p=0.76) (Table 7.6).

Stage shifts were cross tabulated according to spirometry feedback and univariate logistic regression analyses were performed by fitting models for the effect of the category of lung function feedback (NLF versus OLF) on stage shifts and all other potential explanatory variables that might influence smoking cessation. Interaction between feedback and other predictor variables was examined for possible effect modification.

Table 7.6: Distribution of stages in the Transtheoretical Model by spirometry feedback groups at baseline and follow up.

Transtheoretical Model Stage	*NLF (%)*		*OLF (%)*	
	Baseline n=193	3 months n=172	Baseline n=135	3 months n=125
Precontemplation	87 (45.1)	68 (39.5)	60 (44.4)	47 (37.6)
Contemplation	74 (38.3)	67 (39.0)	53 (39.3)	45 (36.0)
Preparation	32 (16.6)	29 (16.9)	22 (16.3)	24 (19.2)
Action		8 (4.7)		9 (7.2)

7.4.2.1 Univariate analysis of stage shift according to spirometry feedback

The primary outcome, stage shift, was compared between participants in the NLF and the OLF feedback groups (Table 7.6). Overall, 181 (60.9%) participants had no change of stage at three months follow up. There was more forward stage shift, towards cessation, in 81 (27.3%) participants compared to backward stage shift in 37 (11.8%) participants. There was a relatively greater forward shift in the OLF group (31.2%) than the NLF group (24.4%), though the difference was not statistically significant (p=0.40). Negative stage shift was almost identical, occurring in 11.6% of the NLF feedback group and 12.0% of the OLF feedback group.

Table 7.7: Stage shift in the Transtheoretical Model for participants in spirometry feedback groups at three month follow up.

	NLF n=172 (%)	*OLF* n=125 (%)	*All* n=297 (%)
Shift forwards	42 (24.4)	39 (31.2)	81 (27.3)
Shift backwards	20 (11.6)	15 (12.0)	35 (11.8)
No change	110 (64.0)	71 (56.8)	181 (60.9)

(NLF= normal lung function, OLF =obstructive lung function)

7.4.2.2 Predictors of stage shift between baseline and follow up

Multinomial logistic regression to predict change of stage from baseline (see Section 7.2.4.1) was used to investigate the predictor variable of primary interest in this study: feedback given to smokers on lung function after spirometry. The two categories were OLF, with changes caused by smoking, and NLF, with no evidence of damage due to smoking. Data on stage of change were only available for 297 smokers included in the analysis (31 missing). The designated reference category in the analyses was "no stage shift" and odds ratios for forward shift and backward shift in univariate analyses were calculated with confidence intervals and *p*-values and are shown in Tables 7.8 and 7.9.

In comparison with smokers with no change, smokers with forward stage shift were 44% more likely to be in the OLF feedback group than the NLF feedback group. However, as the confidence interval for the odds ratio included the value 1.0, the increase in odds ratio was not statistically significant (p=0.18). In comparison with smokers with no stage shift, smokers with backward stage shift were 16% more likely to be in the OLF group, but as the confidence interval included the value 1.0 this increase was not statistically significant (p=0.69). There was thus no increase in odds of backward stage shift compared with no change for feedback on NLF (reciprocal of 1.16), OR = 0.86, 95% CI 0.44 to 1.79 (p=0.69).

The effects of other variables that might influence the intentions of a smoker towards smoking cessation were also examined using univariate multinomial logistic regression analyses. The predictor variables examined were: gender, age, self-report of a respiratory diagnosis, smoking exposure, nicotine dependence, self-efficacy for smoking cessation, social support for cessation by family or friends, and self-rated beliefs about general health, lung damage from smoking and the benefits of quitting smoking (Tables 7.8 and 7.9).

Age and gender were not associated with forward or backward stage shift.

There was a significant increase in odds for positive stage shift compared to no stage shift for smokers reporting a diagnosis of respiratory disease, OR= 2.54, 95% CI 1.42 to 4.57 (p =0.002). Although higher self-efficacy for smoking cessation was associated with increased odds of forward shift and decreased odds of backward shift compared to no change, the results were not statistically significant. The odds of forward shift were decreased if there was lower support from family and friends for smoking cessation, but again the reduction in odds ratio failed to reach statistical significance (p=0.10).

There was a significant association of increased self-rated general health with increased odds of forward stage shift (p =0.02). The association of increased self-rated lung damage with increased odds of forward shift did not quite achieve statistical significance (p= 0.06). The association of higher self-rated benefits of quitting with increased odds of forward shift was not statistically significant (p=0.22).

Only increased self-rated general health was significantly associated with odds of backward shift and this relationship was negative (i.e. lower odds of moving backwards, p=0.02). Neither the association of increasing odds of backward shift with increasing scores for self-rated lung damage (p=0.46) nor increased smoking exposure (p=0.14) were significant in univariate analyses.

Table 7.8 Predictors of stage shift at three months post-spirometry from univariate multinomial logistic regression analysis using reference category of no change.

	Backward shift			No change	Forward shift		
	n *	OR	(95% CI) †	n *	n *	OR	(95% CI) †
Spirometry feedback							
NLF	20	1.00		110	42	1.00	
OLF	15	1.16	(0.59, 2.42)	71	39	1.44	(0.85, 2.44)
		p =	0.69			*p* =	0.18
Age	35	0.99	(0.96, 1.03)	181	81	1.01	(0.98, 1.03)
		p =	0.64			*p* =	0.64
Gender							
Male	18	1.00		77	35	1.00	
Female	17	0.70	(0.34, 1.44)	104	46	0.97	(0.57, 1.65)
		p =	0.33			*p* =	0.92
Respiratory diagnosis							
Not reported	25	1.00		147	51	1.00	
Reported	10	1.73	(0.76, 3.94)	34	30	2.54	(1.42, 4.57)
		p =	0.19			*p* =	0.002
Self-efficacy							
Lower	23	1.00		106	40	1.00	
Higher	12	0.74	(0.35, 1.57)	75	41	1.45	(0.86, 2.45)
		p =	0.43			*p* =	0.17
Social support							
Higher	23	1.00		113	59	1.00	
Lower	12	0.87	(0.41, 1.85)	68	22	0.62	(0.35, 1.10)
		p =	0.71			*p* =	0.10

* n = number of subjects. † OR (95% CI) = odds ratio (95% confidence interval). The crude OR indicates the increase of the odds for a 1-point increase on the scale or compared to the reference group

Table 7.9 Predictors of stage shift at three months post-spirometry from univariate multinomial logistic regression analysis using reference category of no change.

	Backward shift			None	Forward shift		
	n *	OR	(95% CI) †	n*	n *	OR	(95% CI) †
Heaviness of Smoking Index							
0–2	17	1.00		54	31	1.00	
3	13	0.44	(0.15, 1.24)	62	23	0.65	(0.34, 1.24)
4–6	5	1.17	(0.52, 2.68)	65	27	0.72	(0.39, 1.36)
Linear trend		*p* =	0.59			*p* =	0.32
Pack-years of smoking							
6.0–20.0	6	1.00		55	27	1.00	
20.1–40.0	18	2.01	(0.75, 5.39)	82	32	0.79	(0.43, 1.47)
40.1–145.0	11	2.29	(0.79, 6.69)	44	22	1.02	(0.51, 3.84)
Linear trend		*p* =	0.14			*p* =	0.99
Self-rated general health							
0–49	17	1.00		51	17	1.00	
50–69	13	0.53	(0.24, 1.18)	74	29	1.18	(0.59, 2.36)
70–100	5	0.29	(0.10, 0.84)	52	33	1.90	(0.94, 3.84)
Linear trend		*p* =	0.02			*p* =	0.02
Self-rated lung damage							
0–49	10	1.00		64	27	1.00	
50–69	12	1.32	(0.53, 3.29)	58	27	1.10	(0.58, 2.09)
70–100	13	1.41	(0.58, 3.46)	59	27	1.08	(0.57, 2.06)
Linear trend		*p* =	0.46			*p* =	0.06
Self-rated quit benefit							
0–80	10	1.00		46	16	1.00	
81–99	6	0.58	(0.19, 1.71)	48	20	1.20	(0.55, 2.59)
100	19	1.04	(0.44, 2.42)	84	44	1.51	(0.76, 2.96)
Linear trend		*p* =	0.77			*p* =	0.22

* n = number of subjects. † OR (95% CI) = odds ratio (95% confidence interval). The crude OR indicates the increase of the odds for a 1-point increase on the scale or compared to the reference group

7.4.4.3 Interaction on spirometry feedback of other predictor variables

The results of further analysis of spirometry feedback using binary logistic regression are shown in Table 7.10. Adjusting the effect of a report of obstructive lung function for pack-years of smoking, the odds of a forward shift were increased 1.74 times (95% CI 0.99 to 3.06) which is very close to a statistically significant outcome

The interaction of lung function feedback with health beliefs was also examined. For these analyses and with the agreement of a professional statistician, two particularly poorly-fitted subjects in the binary model of forward shift versus no change, with values of the Pregibon Db influence statistic that were 97% and 58% higher than the Db-value for the next most poorly-fitted subject were excluded (316). The *p*-value for the interaction is the result of a test of significance of a (feedback x self-rated quit benefit) product term in a logistic regression model that also included a binary covariate for spirometry feedback and a linear covariate for self-rated quit benefit. The odds of backward shift varied with self-rated benefit from quitting (interaction $p=0.05$). Thus, among subjects who rated the quit benefits very highly (90 or higher), those who received feedback of lung damage due to smoking (OLF) had (rather paradoxically) higher odds of reverting to an earlier stage of reduced motivation to quit than did those who received a report of normal lung function. Among subjects who rated the quit benefits less highly (less than 90), this report of damaged lungs was associated with reduced odds of a backward shift. Self-assessments of the benefits of quitting were positively correlated with self-rated lung damage ($r = 0.27$) as reported in section 7.3.2.3, and precisely the same pattern of interaction was found with self-rated lung damage in place of self-rated quit benefit (data not shown). Thus, those smokers with high personal assessment of damage from smoking were more likely to regress if told they had OLF, but in this case the association was not statistically significant ($p=0.44$).

Table 7.10: Binary associations of spirometry feedback with stage shift in the Transtheoretical model of smoking cessation at 3 months post-spirometry

	Backward shift			Forward shift		
	n / N *	OR	(95% CI) †	n / N *	OR	(95% CI) †
Spirometry feedback, unadjusted						
Normal lung function	20/130	1.00		42/152	1.00	
Obstructive lung function	15/86	1.16	(0.59, 2.42)	39/110	1.44	(0.85, 2.44)
		p =	0.40		*p* =	0.18
Spirometry feedback, adjusted						
Normal lung function	20/127	1.00		40/150	1.00	
Obstructive lung function	15/84			39/110	1.74	(0.99, 3.06) ‡
– self-rated quit benefit = 40		0.06	(0.00, 1.64) §		*p* =	0.05
– self-rated quit benefit = 80		0.63	(0.20, 1.99) §			
– self-rated quit benefit = 90		1.14	(0.50, 2.60) §			
– self-rated quit benefit = 100		2.05	(0.86, 4.80) §			
Test of interaction		*p* =	0.05^			

* n / N = number of subjects with this type of shift / total number of subjects in this feedback category. † OR(95% CI) = odds ratio (95% confidence interval).

‡ Adjusted for pack-years of smoking.

§ Adjusted for self-rated quit benefit and self-rated general health, and calculated at the value of self-rated quit benefit shown.

7.4.3 Three month self reported sustained smoking cessation

Overall 17 (5.2%) participants reported sustained smoking cessation three months after spirometry, 8 (4.1%) in the NLF group and 9 (6.7%) in the OLF group. The quit rate in the OLF group for those classified with mild obstruction was 6.8% and 7.4% for moderate obstruction, but none of the seven smokers with severe or very severe obstruction quit smoking. The difference in smoking cessation rates at 3 months between participants in the NLF group and those in OLF group was not statistically significant (p=0.31). There was no significant difference in the proportions of smokers who quit amongst the practices (Fisher's, p=0.86) (Table 7.11).

Table 7.11: Participants with sustained smoking cessation at three month follow up by practice.

Practice	*OLF*		*NLF*		*ALL*
	n	N (%)	n	N (%)	% ‡
1	3	29 (10.3)	0	37 (0)	4.5
2	1	16 (6.3)	1	30 (3.3)	4.3
3	1	33 (3)	1	25 (4)	3.4
4	0	9 (0)	2	20 (10)	6.9
5	3	30 (10)	3	32 (9.4)	9.7
6		8 (12.5)	0	16 (0)	4.2
7	0	9 (0)	1	27 (3.7)	2.8
8	0	1 (0)	0	6 (0)	0
ALL	9	135 (6.7)	8	193 (4.1)	5.2

(n = number of participants with sustained cessation, N = number of participants recruited in practice, ‡ percentage of all participants with sustained cessation in the practice)

7.4.3.1 Comparison of participants achieving sustained smoking cessation (n=17) and continuing smokers (n=311)

7.4.3.1.1 Demographics, spirometry, smoking behaviour, self-efficacy, social support

Seventeen (6M/11F) participants achieved sustained smoking cessation according to the study definition at three-month follow up, with no significant differences in gender distribution, current age or age of starting smoking between quitters and non-quitters. Quitters had lower smoking exposure (mean difference 13.5 pack years) and lower nicotine dependency (mean difference 1.2 Heaviness of Smoking Index) and both differences reached statistical significance (Table 7.12).

A significantly greater proportion of quitters (47.1% versus 22.7%) reported an existing doctor diagnosed respiratory condition (Table 7.12). The proportion with functional dyspnoea of Grade 3/4 (41.1%) was higher than the proportion in non-quitters (21.4%) although the overall distribution of dyspnoea severity grades between those who quit and continuing smokers was not significant (p=0.08).

There were no significant differences in any parameter of spirometry measured, FEV1, FVC, FEV1/FVC ratio, PEF or $FEF_{25-75\%}$, between those who quit and continuing smokers (data only shown for FEV1 % predicted in Table 7.12). The difference between proportions of quitters and non-quitters in the OLF feedback group (52.9% versus 40.5%) was not statistically significant (p=0.31).

However, there was a significant difference in the distribution of participants' baseline stage of change between quitters and continuing smokers (p=0.01). A stage effect was seen with a higher proportion of those that quit being in the preparation stage before spirometry, 41.2% compared to 15.1% of non-quitters.

There was a statistically significant difference in distribution of self-efficacy categories (p <0.01) between quitters and continuing smokers, with 35.3% of quitters feeling very confident at baseline that they could quit compared to 15% in the non-quitters. Quitters in both feedback groups (OLF versus NLF) had higher self-efficacy scores than smokers who continued smoking (Figure 7.5). However, there was no difference in the distribution of categories of social support with 47.1% of quitters and 40.7% of non-quitters reporting that their family and friends very much wanted them to quit.

No significant differences were found for the proportions of participants living alone or having an educational qualification beyond grade 12 between quitters and non-quitters.

Figure 7.5: Distribution of smoking cessation self-efficacy categories after feedback on OLF or NLF by quit status at three month follow up

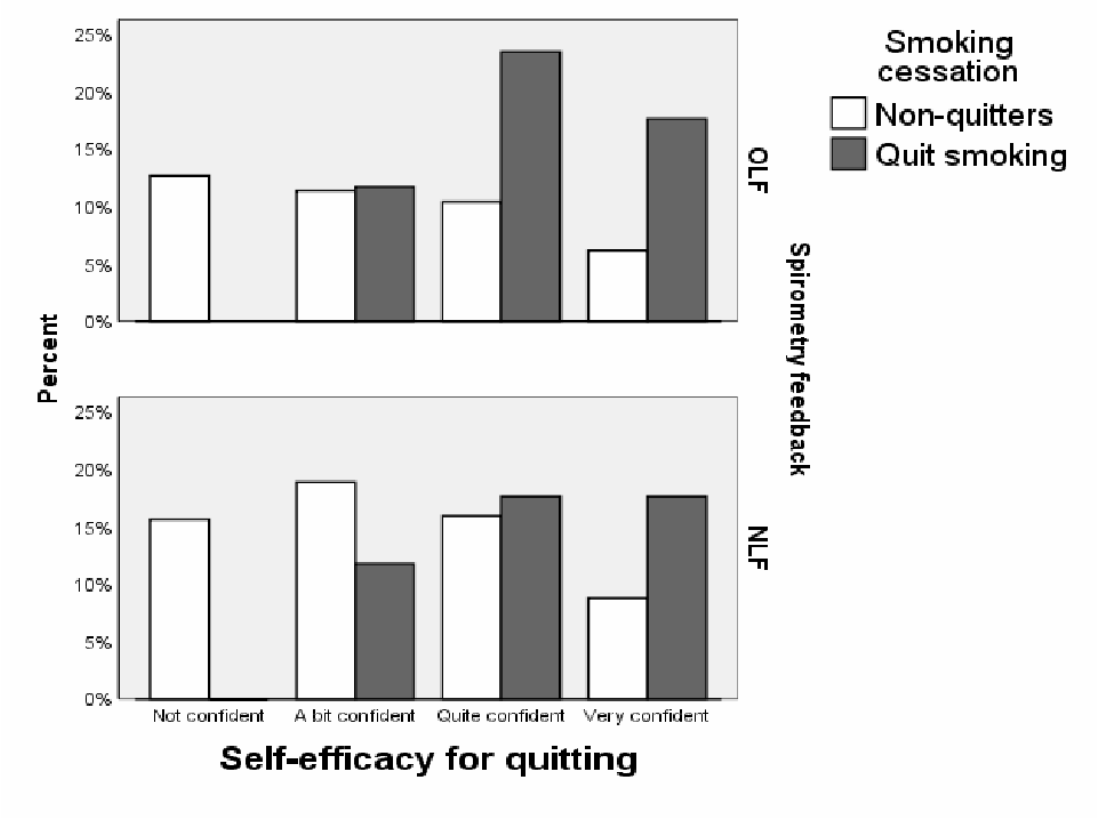


Table 7.12: Baseline characteristics of participants by smoking status at follow up.

Smoking status at follow up		*Quit*	*Not quit*	
		n=17	*n=311*	*p value*
Age (years)[†]		54.6 (14.4)	49.5 (10.0)	0.16
Age starting smoking (years)[‡]		17 (5)	16 (4)	0.10
Male (%)		6 (35.3)	140 (45.0)	0.30
Cigarettes/day[‡]		10 (10)	20 (12)	<0.01
Smoking exposure[1 ‡]		18.6 (17.3)	28.0 (23.8)	<0.01
Nicotine dependence[2 †]		1.9 (1.6)	3.1 (1.5)	<0.01
Respiratory diagnosis (%)		8 (47.1)	71 (22.7)	0.04
Inhaled medication use (%)		6 (35.3)	50 (16.1)	0.05
Spirometry feedback OLF (%)		9 (52.9)	126 (40.5)	0.31
FEV1 % predicted[†]		97.4 (21.7)	93.6 (19.3)	0.43
Transtheoretical model stage	Precontemplation (%)	3 (17.6)	144 (46.3)	
	Contemplation (%)	7 (41.2)	120 (38.6)	0.01
	Preparation (%)	7 (41.2)	47 (15.1)	
Functional dyspnoea	None	6 (35.3)	78 (25.2)	
	MRC Grade 1	2 (11.8)	53 (17.2)	
	MRC Grade 2	2 (11.8)	112 (36.2)	0.08
	MRC Grade 3	3 (17.6)	24 (7.8)	
	MRC Grade 4	4 (23.5)	42 (13.6)	
Living alone (%)		9 (52.9)	133 (43.9)	0.47
Educational qualification after GR 12		6 (35.3)	112 (36.4)	0.93
Very confident about quitting (%)		6 (35.3)	36 (15.0)	<0.01
Significant others support quitting: very much (%)		8 (47.1)	125 (40.7)	0.53

([†] Mean and SD, [‡] Median and IQR, [1] Pack years, [2] Heaviness of smoking index 0-6.

7.4.3.1.2 Health beliefs at baseline

There was a significant difference between subsequent quitters and non-quitters in their self-rated general health prior to spirometry. With the range of scores from zero indicating much worse than average to 100 indicating much better than average, the median score for quitters was 80.0 (IQR 30) and 51 (IQR 24) for non-quitters ($p<0.01$). The distribution of scores is shown in Table 7.13. Significantly more quitters (62.5%) rated their general health in the highest scoring band (70-100) than non-quitters (30.3%) ($p=0.02$)

Assessments of the presence of lung damage self-rated from lowest possible (0=not at all likely) to highest (100=very likely) were similar for both quitters and non-quitters, median scores both 70 (IQR 65) and 70 (IQR 41) respectively. Assessment of the benefits of quitting, from zero (not at all important) to 100 (very important) were similar with median scores of 100 (IQR 14) and 97 (IQR 20) for quitters and non-quitters respectively. There was no significant difference in distribution of bands for scores of either self-rated lung damage ($p=0.52$) or the benefits of quitting ($p=0.52$) between quitters and non-quitters. Around 50% of those who quit and those who continued smoking rated their lung damage between 70-100 on the visual analogue scale.

Table 7.13: Self-rated attitudes to health and smoking in quitters and non-quitters at follow up. (Number of participants varies where data was missing)

		Quit	*Not quit*
Self-rated general health		*(n=16)*	*(n=304)*
(0=much worse than	0-49	1 (6.3)	89 (29.3)
average, 100=much	50-69	5 (31.3)	123 (4.05)
better than average	70-100	10 (62.5)	92 (30.3)
		Fisher's $p = 0.02$	
Self-rated quit benefits		*(n=17)*	*(n=307)*
(0= not at all	0-80	3 (17.6)	78 (25.4)
important, 100= very	81-99	3 (17.6)	78 (25.4)
important)	100	11 (64.7)	151 (49.2)
		Fisher's $p = 0.52$	
Self-rated lung damage		*(n=16)*	*(n=307)*
(0=not at all likely,	0-49	5 (31.3)	64 (20.8)
100= very likely)	50-69	3 (18.8)	88 (28.7)
	70-100	8 (50.0)	155 (50.5)
		Fisher's $p = 0.52$	

7.4.3.2 Logistic regression models for smoking cessation

Univariate logistic regression analyses were performed, by fitting a model for the effect of the category of lung function feedback (NLF versus OLF) on sustained smoking cessation, and all other potential explanatory variables that might influence smoking cessation. Interaction between feedback and other predictor variables was examined and a multivariate model that best predicted quitting was fitted.

7.4.3.2.1 Univariate analysis (Table 7.14)

For participants in the OLF feedback group, there was an increase in odds of quitting smoking (OR 1.65; 95% CI 0.62 to 4.40) by three months but the confidence interval crosses the line of zero effect (p=0.32).

Sustained smoking cessation was not associated with living with a partner (n=237, 74%) compared to living alone (n=83, 26%), OR 0.70, 95% CI 0.26 to 1.85 or whether an education qualification of at least grade 12 was attained (Yes n=144, 44%; No n=181, 56%), OR 0.67, 95% CI 0.24 to 1.86. When support for cessation from significant others was dichotomised into not at all/only a little (n=110, 34%) and quite a lot/very much (n=214, 66%), having greater encouragement was not significantly associated with quitting (OR 1.28, 95% CI 0.44 to 3.72). The grade of functional dyspnoea was not associated with likelihood of quitting (Table 7.14).

Predictor variables with statistically significant effects on the odds ratio for quitting smoking (Table 7.14) were: increasing age (one year increase 4%; 95% CI 0 to 9), increasing number of cigarettes smoked per day (1 cigarette per day decrease 10%; 95% CI 7 to 16), increasing nicotine dependence (one unit increase in HSI decrease 40%; 95% CI 19 to 32) and increasing smoking exposure (one year increase in pack years decrease 4%; 95% CI 4 to 7).

Self-report of a respiratory diagnosis was associated with a 3-fold increase in the odds of sustained smoking cessation while being in the preparation stage of change compared to the precontemplation stage was associated with a 7-fold increase (Table 7.14). When self-efficacy was dichotomised into not confident/only a bit confident and quite confident/very confident, having higher self-efficacy was associated with a 4-fold increase in likelihood of sustained cessation (Table 7.14)

The odds of quitting smoking were 9-fold higher for participants whose self-rated beliefs about their general health were in the highest band compared to the lowest band (Table 7.15) and the test for linear trend was significant, p<0.01.

The association between higher self-rating of lung damage and lower odds of quitting was not statistically significant. There was no significant association between the self-rated benefits of quitting and smoking cessation (Table 7.15).

7.4.3.2.2 Interaction between lung function feedback and other variables

In order to fully explore any relationship between the feedback categories of lung function, logistic regression models were generated in which the effect of spirometry feedback (NLF or OLF) was adjusted for a second covariate. All potential predictor variables were examined. When spirometry feedback category was adjusted for the number of pack years of smoking, the association with feedback on OLF was stronger and closer to achieving statistical significance (OR= 2.44; 95% CI 0.88 to 6.75, p= 0.09). However, there were no significant interactions with any other variables measured (data not shown).

7.4.3.2.3 Interaction between lung function feedback and other variables

Logistic regression models were fitted using variables that were associated with sustained quitting at three months in univariate analyses with $p<0.10$. An initial model, without stepwise variable selection was examined and variables with weak associations were removed individually from subsequent models while retaining the variable of prime interest in the study, i.e. feedback on spirometry (277). Heaviness of smoking index (HSI) and the daily cigarette consumption were significantly associated with each other such and HSI was retained in the model as a validated measure of nicotine dependence. Being in the preparation stage of the Transtheoretical Model and having higher self-rating for general health remained significant predictors for quitting in a model that also included spirometry feedback, nicotine dependence and self-efficacy (Table 7.16). The value of Nagelkerke's R^2 was 0.26, indicating that about 26% of the variation in the outcome smoking cessation at three months was explained in total by this model.

Table 7.14: Predictors of sustained smoking cessation at three month follow-up

Predictor variables		n	OR[a]	95% CI	*p* value
Gender	Male	146	0.67	0.24, 1.85	0.44
	Female	182	1	Reference	
Age (years)		328	1.04	1.00, 1.09	0.05
Age start smoking (years)		326	1.07	0.99, 1.16	0.08
Cigarettes/day		325	0.90	0.84, 0.97	<0.01
HSI		325	0.60	0.43, 0.84	<0.01
Smoking history (pack years)		313	0.96	0.93, 0.99	0.03
Spirometry feedback					
	OLF	135	1.65	0.62, 4.40	0.32
	NLF	193	1	Reference	
Transtheoretical Model stage					
	Preparation	54	7.15	1.78, 28.76	<0.01
	Contemplation	127	2.80	0.71, 11.06	0.14
	Precontemplation	147	1	Reference	
Respiratory diagnosis reported					
	Yes	79	3.01	1.12, 8.07	0.03
	None	235	1	Reference	
Functional dyspnoea					
	None	84	1	Reference	
	MRC grade 1	55	0.49	0.10, 2.52	0.39
	MRC grade 2	114	0.23	0.05, 1.18	0.08
	MRC grade 3	27	1.63	0.38, 6.99	0.51
	MRC grade 4	46	1.24	0.33, 4.63	0.75
Confidence in quit ability					
	Higher	140	4.65	1.48, 4.58	<0.01
	Lower	184	1	Reference	

[a] OR from univariate logistic regression, indicating the increase of the odds for a 1-point increase on the scale or compared to the reference group. Number in analyses (n) varies with missing data.

Table 7.15: Association between health beliefs and sustained smoking cessation at three month follow-up

Predictor variables		n	OR[a]	95% CI	*p* value
Self-rated general health					
VAS bands	0-49	91	1	Reference	
	50-69	128	3.62	0.42, 31.51	0.24
	70-100	102	9.67	1.21, 77.14	0.03
	Linear trend	$p<0.01$			
Self-rated lung damage					
VAS bands	0-49	69	1	Reference	
	50-69	91	0.44	0.10, 1.89	0.27
	70-100	163	0.66	0.21, 2.10	0.48
	Linear trend	$p=0.56$			
Self-rated quit benefit					
VAS bands	0-80	81	1	Reference	
	81-99	81	1.00	0.20, 5.11	1.00
	100	162	1.89	0.51, 7.00	0.34
	Linear trend	$p=0.27$			

[a] OR from univariate logistic regression, indicating the increase of the odds for a 1-point increase on the scale or compared to the reference group. Number in analyses (n) varies with missing data.

Table 7.16: Predictors of sustained smoking cessation at three month follow up in a multivariate logistic regression model

Variable	*n*	*OR*[b]	*95% CI*		*p value*
Baseline TTM stage					
Precontemplation	141	1	Reference		
Contemplation	123	3.43	0.68	17.31	0.14
Preparation	50	10.72	1.87	61.52	<0.01
Self reported general health					
0-49	87	1	Reference		
50-69	127	3.89	0.42	35.82	0.23
70-100	100	10.25	1.14	91.93	0.04
Linear trend		*p*=	0.04		
Self-efficacy					
Lower	179	1	Reference		
Higher	135	2.66	0.78	91.93	0.12
Feedback on spirometry					
NLF	187	1	Reference		
OLF	127	1.45	0.49	4.31	0.51
Heaviness of Smoking Index (0-6)	314	0.71	0.48	1.03	0.07

[b] OR (95%CI)= odds ratio and 95% confidence interval from multivariate logistic regression, indicating the increase of the odds for a 1-point increase on the scale or compared to the reference group. Number in analyses (n) varies with missing data.

7.4.4 Attempts to quit smoking

7.4.4.1 Proportions making one or more attempts to quit smoking

At least one attempt to quit smoking, defined as abstinence for at least 24 hours, was made by 99 (31.7%) participants completing follow up, equivalent to 30.2% of the whole cohort. Proportions making a quit attempt were not significantly different between feedback groups, 45 (35.2%) in the OLF group and 54 (29.3%) in the NLF group (p=0.28) (Table 7.17).

There was no significant difference between feedback groups in the number of quit attempts made during three months (p=0.95). Just over 10% of both groups made four or more attempts to quit that were not sustained (Table 7.18).

7.4.4.2 Regression analysis for attempts to quit smoking

Significant predictors for attempting to quit smoking are shown in Table 7.19. Smokers who attempted to quit smoking were significantly older when they started smoking and had lower nicotine dependency. Smokers with smoking exposure exceeding 20 pack years had lower odds of attempting to quit. Those who reported a respiratory diagnosis and those with higher confidence in their ability to quit smoking had higher odds of attempting to quit.

Smokers who gave a rating of 100/100 for their perceptions of the benefits of quitting were over twice as likely to make a quit attempt as those giving a rating of 80 or lower. Compared to smokers in the precontemplation stage for smoking cessation at baseline, those in later stages had higher odds of attempting to quit; three fold higher for contemplation stage and six fold higher for preparation stage (Table 7.19).

Table 7.17: Participants making at least one quit attempt at three month follow up by practice.

Practice	*OLF*		*NLF*		*ALL*
	n	N *(%)*	n	N *(%)*	%‡
1	10	29 (34.5)	7	37 (18.9)	25.8
2	5	16 (31.3)	5	30 (16.7)	21.7
3	6	33 (18.2)	4	25 (16.0)	17.2
4	2	9 (22.2)	8	20 (40.0)	34.5
5	15	30 (50.0)	12	32 (37.5)	43.5
6	3	8 (37.5)	9	16 (56.3)	50.0
7	3	9 (33.3)	6	27 (22.2)	25.0
8	1	1 (100.0)	3	6 (50.0)	57.1
ALL	45	135 (28.0)	54	193 (33.3)	30.2

(n = number of participants making quit attempt, N = number of participants recruited in practice, ‡ percentage of all participants in the practice making a quit attempt)

Table 7.18: Number of attempts to quit smoking by participants in NLF and OLF groups

Number of quit attempts	*NLF n=193 (%)*	*OLF n=135 (%)*	*Total n=328 (%)*
None	139 (72.0)	90 (66.7)	229 (69.8)
One	18 (9.3)	18 (13.3)	36 (11.05)
Two	12 (6.2)	9 (6.7)	21 (6.4)
Three	5 (2.6)	4 (3.0)	9 (2.7)
Four or more	19 (10.3)	14 (10.9)	33 (10.1)

Table 7.19: Univariate logistic regression analyses with making a quit attempt as the outcome.

Predictor variables		*n*	*OR**	*95% CI*	*p value*
Age started smoking (years)		310	1.06	1.01, 1.11	<0.05
Heaviness of smoking index (0-6)		309	0.61	0.51, 0.73	<0.0001
Smoking exposure (pack years)	≤20	86	1	Reference	
	>20	212	0.31	0.18, 0.52	<0.0001
Feedback[†]	NLF	140	1	Reference	
	OLF	128	1.31	0.81, 2.11	0.28
TTM[§] stage at baseline-	Precontemplation	140		Reference	
	Contemplation	122	3.30	1.86, 5.87	<0.0001
	Preparation	50	6.47	3.17, 13.24	<0.0001
Report respiratory diagnosis	No	221		Reference	
	Yes	77	2.24	1.31, 3.83	<0.01
Self-efficacy	Lower	134		Reference	
	Higher	175	2.01	1.24, 3.27	<0.01
Self-rated quit benefit (VAS scale)	0-80	76	1	Reference	
	81-99	76	1.54	0.74, 3.21	0.25
	100	153	2.42	1.28, 4.59	<0.01
	Linear trend	p= <0.01			

Results for univariate analyses shown as *Crude odds ratio and 95% confidence interval (CI). [†] Spirometry feedback on normal lung function (NLF) or obstructive lung function (OLF). [§] TTM=Transtheoretical Model

7.4.5 Change in cigarette smoking

Amongst the 311 participants in the cohort who continued to smoke at three month follow up data on the change in number of cigarettes smoked per day were available for 265 (85.2%) participants (Table 7.20). The majority (76.6%) of smokers did not report a change in consumption. A significantly larger proportion in the OLF feedback group (p=0.03) reported decreasing consumption by more than 5 cigarettes per day compared to the NLF feedback group (28.3% v. 15.1%). Very few smokers reported an increase in daily consumption of more than 5 cigarettes per day.

Table 7.20: Change in daily cigarette consumption in continuing smokers by spirometry feedback group

Cigarettes per day	*NLF*	*OLF*	*All*
	n=159 (%)	n=106 (%)	n=265 (%)
Increase >5/day	5 (3.1)	3 (2.8)	8 (3.0)
No change	130 (81.8)	73 (68.9)	203 (76.6)
Decrease > 5/day	24 (15.1)	30 (28.3)	54 (20.4)

7.4.6 Results of data extraction from practice records

7.4.6.1 Sample for practice records data on smoking

Sustained smoking cessation at three month follow up was achieved by 11 (5.7%) smokers recruited in Period 1 and 6 (4.4%) smokers recruited in Period 2. There was no significant difference between the proportions quitting recruited in each period (chi-squared 0.255, p= 0.61). For the first six months of the study (Period 1), practice records for recruited smokers were examined and data extracted on changes following spirometry in diagnosis, management and further investigations performed (see methods, chapter 4.10.16). Of the total cohort of smokers recruited (n=328), 193 (58.8%) were recruited in Period 1, of whom data extraction was successfully completed for 174 (90.2%). Results in this section are therefore based on smokers recruited in Period 1only.

7.4.6.2 Recording of smoking status and advice or assistance with smoking cessation

Prior to spirometry, 67 (38.5%) participants did not have a record of their smoking status and around 54% in both spirometry feedback groups had a correct record of current smoking status (Table 7.21).

By three months after spirometry, the proportions without a recent record for smoking status had not fallen at all. Fewer than 50% of actual smokers who had not quit were then correctly recorded as a current smoker in both spirometry feedback groups. As already described, all current smokers participating in the study in TN practices received standard brief smoking cessation advice from a trained nurse. All smokers undergoing spirometry were given a Quit book (Tasmanian edition) containing advice on methods of quitting and contact details for support agencies. Any further advice on smoking cessation given by a GP was recorded for 32 (18.4%) smokers overall. There were no significant differences in the proportions with a record of advice on cessation between those with OLF and NLF (p=0.24) (Table 7.21) or between those who quit and continuing smokers (p=0.42) (data not shown). Specific assistance with quitting, e.g. nicotine replacement or bupropion, was very infrequently recorded (Table 7.22), overall around 90% had no record of receiving any assistance. There was no significant difference between those with OLF or NLF (p=0.99) or between those who quit and continuing smokers (p=0.15) in the proportions with a record of specific assistance with cessation. Only two participants who quit had any specific assistance recorded, with both receiving bupropion.

Table 7.21: Doctor-recorded smoking status, cessation advice and assistance three months following spirometry in relation to spirometry feedback

Practice record	*NLF*	*OLF*	*All*
	n=88 (%)	*n=87 (%)*	*n=174 (%)*
Smoking status pre-spirometry:			
Not recorded	35 (39.8)	32 (37.2)	67 (38.5)
Correctly recorded as smoker	48 (54.5%)	46 (53.5%)	94 (54.0%)
Smoking status 3 months post-spirometry:			
Not recorded	55 (62.5)	46 (53.5)	101 (58.0)
	*n=84 (%)	*n=79 (%)	*n=163 (%)
Correctly recorded as smoker	31 (36.9)	38 (48.1)	69 (42.3)
Smoking cessation:	*n=88 (%)*	*n=87 (%)*	*n=174 (%)*
Cessation advice recorded	13 (14.7)	19 (21.8)	32 (18.4)
Cessation assistance recorded	10 (11.4)	9 (10.3)	19 (10.9)
NRT	2 (2.3)	1 (1.2)	3 (1.7)
Bupropion	3 (3.4)	3 (3.5)	6 (3.5)
Referral	1 (1.1)	2 (2.3)	3 (1.7)

(NLF= normal lung function, OLF =obstructive lung function, * number of smokers who had not quit at three months, NRT= nicotine replacement therapy)

Table 7.22 Doctor-recorded assistance with smoking cessation in relation to smoking status three months following spirometry.

Assistance	*Quit*	*Not quit*
	n=11 (%)	n=163 (%)
None	9 (81.8)	147 (90.2)
Type given:		
Referral		3 (2.0)
NRT		3 (2.0)
Bupropion	2 (18.2)	4 (2.6)
Hypnosis		1 (1.0)

7.5 Discussion

7.5.1 Overview

This study recruited a cohort of 328 smokers through the use of trained nurses who performed spirometry opportunistically in general practices over a twelve month period. There was over 90% successful follow up three months after spirometry. The intervention consisted of a simple statement by the trained nurse on the result of spirometry i.e. the presence of changes in lung function suggesting lung damage due to smoking or the presence of normal lung function without signs of damage due to smoking. Although the age composition and lung function of the two feedback groups differed, they were similar for factors that might influence smoking cessation: nicotine dependence, the number of cigarettes smoked daily, proportions in three stages of change according to the Transtheoretical Model of smoking cessation and proportions that had made an attempt to quit recently. The effect of demonstrating airflow limitation on spirometry and giving immediate feedback on the results to smokers resulted in forward shift in the stages of change model of smoking cessation in 27%, backward stage shift in 12% and actual smoking cessation in just over 5% of the cohort.

7.5.2 Primary outcome

The primary outcome of interest was change in intention to stop smoking after spirometry and feedback on obstructive lung function (OLF). This was associated with higher odds of forward shift compared to feedback on normal lung function (OR 1.44; 95% confidence interval 0.85 to 2.44) that became stronger on adjustment for pack-years of smoking (OR 1.74; 95% confidence interval 0.99 to 3.06). The significance level just fell short of the conventional level, probably reflecting a type II error associated with the sample size. However, and very importantly for clinical practice, feedback on normal lung function was not associated with higher odds of backward shift compared to feedback on obstructive lung function, OR 0.86; 95% confidence interval 0.44 to 1.79 (p =0.69). This is unlikely to be a statistical error as any effect is very small.

The odds of a backward shift to an earlier stage of quitting for smokers receiving feedback on lung damage, varied with self-assessments of the benefits of quitting. As self-rated quit benefits were positively correlated with perceptions of self-rated lung damage, the subjects more likely to revert to an earlier stage of quitting following a

report of damaged lungs were those who perceived (prior to the feedback) that they had greater lung damage. One possible explanation of this finding is that smokers already pessimistic about their lung function were less likely to be disappointed by the negative feedback after spirometry. Indeed, in these "nihilistic" smokers the result reinforced their pessimism and they were then less motivated to quit because their anticipated damage was confirmed. Conversely, subjects with low self-rated lung damage maintained and did not weaken their motivation to quit following a report of lung damage because, we suppose, they were alarmed by the negative feedback, which shook their complacency.

7.5.3 Attitudes to health and smoking

Measurements of smokers' attitudes to their health, their perception of damage in their lungs from smoking and the benefits they perceived from quitting were unique features of this study of smokers who underwent spirometry in primary care. Other studies have found similar differences to those in this study in self-assessed general health for smokers in different stages of the Transtheoretical Model (317) and in the perceived benefits of quitting (177). Only in this study was the impact of personal attitudes on the effect of feedback on spirometry explored in such detail, permitting the effect of spirometry feedback to be explored more fully than in other similar studies (194,318).

Self-assessment of general health was based in this study on the response to one question that asked participants to compare their health to that of others of the same age. This phrasing was used to allow for the effects of age related conditions. There is an independent association of self-assessed general health with mortality, which was reported in a review of over twenty large longitudinal studies in populations of varying age ranges, and was consistent despite semantic variations in the question used (319). It does seem therefore to be a valid question. General health perception is subjective and thought to represent an integration of physiological variables, symptoms and functional status, distinct from, though related to, quality of life (320,321). There is evidence that self-rating of general health is related to experiencing physical symptoms (322,323), but also that it is more strongly associated with dispositional optimism (324) and fears and beliefs about disease than to objective measures of disease severity (325,326).

This study found that forward shift in the Transtheoretical Model of preparedness to quit smoking, was independently associated with higher baseline global self-rating of

health. Self-rated health assessed before spirometry, was actually lower in smokers in preparation than in smokers in the earlier stages of motivation, an association previously reported in a survey of smokers in Germany (317). This would suggest that those with most concern about their general health are more likely to be prepared to quit.

Other studies have looked at the effect of self-rated health on a variety of outcomes and found an association with recovery from serious illnesses and hospitalisation (327) and change in functional ability (328). In my study both better general health perception and reporting a respiratory diagnosis were associated with positive stage shift and successful smoking cessation.

The possible influence of dispositional optimism and pessimism can only be the subject of speculation, as this was not part of the a priori hypothesis and further investigation if warranted would require a different study. Scheier and Carver have reviewed the research literature in the field of psychology and the effects of optimism on physical functioning (329). They concluded there was objective evidence of benefit on physiological measures although the effects may have been biased by favourable self-report. Investigation of mechanisms for the effects of optimism indicate that one potential pathway lies through active coping skills, in particular the use of problem-focused coping that involves action planning and developing strategies (330). This would be consistent with the outcome in my study/

7.5.4 Influence of population studied

The population of smokers in this study was not selected for high motivation and represents that typically seen in primary care, with only 17% in the preparation stage before spirometry. The proportion of smokers in precontemplation was higher than the 24% found in a 1992 population survey in South Australia (331). On the other hand, there is no evidence that “immotive” or “hard-core” smokers were over-represented in the study population. The definition of the precontemplation stage (having no serious intention of quitting smoking in the next six months) differs from that of “immotive” (317) and “hard-core” (332) (333) smokers. In my study, of the 142 smokers in the precontemplation stage, up to 31 (9.5%) could be classified as “hard core” using the definition in Emery et al of “a heavy smoker with a poor quitting history and no expectation of quitting” (333). However smokers in my study were asked if they had any intention of quitting in the next six months, rather than had no expectation of quitting ever, and thus the actual percentage of such “hard

core" smokers is probably lower. The prevalence of "hard-core" smokers in a survey of adults aged over 25 in the US based on having no expectation of quitting ever, was 5% (333). In the UK, 16% of smokers aged over 16 declared they had no intention of stopping smoking and were classified as "hard core" smokers, with the prevalence rising to 30% of those aged 65 or over (332). However, the survey may over-estimate the prevalence as no time scale was used to define the question.

7.5.5 Other studies using stage shift as an outcome

No comparison with other studies on the effect of spirometry on motivation, using the stages of the Transtheoretical Model was possible as no previous studies were found in comprehensive literature searches, although recent comment on the use of the model has suggested these are necessary (334). This gives the current study added importance.

7.5.6 Stage shift as outcome

In interpreting the results of stage shift among smokers it is important to know the lability/stability for stage of change membership over short periods of time. Among smokers in an Australian population survey of 16-70 year olds, there was a relatively high level of congruence on immediate re-testing for the precontemplation and contemplation stages (83.3% and 84.6%, respectively) although the stages were defined by intentions in a 30-day time frame, rather than the 6-month time frame used to define the stages in the Transtheoretical Model (335). However, stage membership was shown to be predominantly stable in a study in the USA and Sweden using the conventional time periods of the stages of change. Among 56 smokers, 83% were stable for stages when reassessed after 30 days, with 4% showing backward shift and 13% showing forward shift (336). In my study the majority of smokers were stable in their intentions to quit smoking following spirometry when assessed after three months.

A variety of statistical methods have been used in other studies for the analysis of stage shift in the Transtheoretical Model. Latent transition analysis, a method of assessing change in categorical outcomes (185,337), and Markov chain analysis which investigates modelling of sequences of behaviour with discreet stages (168) have both been used to yield transition probabilities of movement through stages. However, neither method was suitable in this study. This is because the initial classification of participants was only to three stages and later classification was

limited to a single follow-up time point less than six months later, thereby preventing measurement of movement into the maintenance stage of the model. Contingency tables and the chi-squared statistic and logistic regression techniques used in this study have been used in other intervention studies to analyse comparable stage shift (169,186).

7.5.7 Stage of change model

There has been criticism of the use of the Transtheoretical Model of stages of preparedness as applied to smoking cessation (173). According to some psychologists, the stages lack some essential characteristics that are required in a model of behaviour change (338). Thus, staging algorithms are based on arbitrary time periods and they may not discrete, as they are not consistent with other measurements of readiness to change for some health-related behaviours, including smoking cessation (339). While it is true that the stage definitions represent a mixture of different types of construct; intention, past quit attempts and time since quitting, constructs by their nature always differ from the phenomenon itself i.e. quitting smoking, and the model is an attempt to operationalise the process of smoking cessation in a useful way (340).

The use of the model to control access to effective smoking cessation interventions has been criticised (173,338,341) although use of the stages to enhance and assist the cessation process has been found valuable by many clinicians (340).

Criticisms of the nature of the model, or whether it is the best model of behaviour change, were not directly addressed in this study. Stage effects, in which the initial baseline stage predicts being in action at follow-up, are highly consistent findings (167,334,338,342) and were supported by the results in this study. The use of shifts in stage of change as an outcome measure to measure progress towards smoking cessation is held to be practical, valid (338) and suited to testing hypotheses in clinical service delivery (334), despite possible inadequacies in the model definitions. In the current study in which the effect of differential feedback on the presence of lung damage demonstrated by opportunistic spirometry was assessed, the use of the Transtheoretical Model seemed to work well as a predictor of quitting and as a reasonable, sensible “content-valid” way to assess movement due to a strategic intervention. In particular, it allowed us to firmly demonstrate the absence of an adverse effect on backward stage shift.

7.5.8 Smoking cessation

Smoking cessation was not the primary outcome in this study, which was not powered to achieve a statistically significant result using cessation as the outcome. However, the increased odds of cessation at three months observed in smokers with feedback on obstructive lung function compared to normal lung function are consistent with the increased odds of quitting (OR 1.56 95% CI 1.24 to 1.95) found in a larger study conducted in Poland (193). In that study, 4,494 smokers were required to actively respond to an invitation to attend for outpatient spirometry screening at a specialist centre, where a specialist physician gave feedback on spirometry. Thus they were likely to have a higher level of concern about their lung health (44) and be more motivated than in this study of smokers approached opportunistically in their GPs' surgery.

There is no evidence that impact of feedback varies if given by a specialist rather than by a nurse. Low intensity nursing interventions are effective in smoking cessation and the effect size in a meta-analysis of six studies was of similar size to the effect of brief physician advice on smoking cessation (143,343). However, the time taken to give feedback and anti-smoking advice by the specialist in those studies was 5-7 minutes and this was considerably longer than the time taken by the nurse in my study in which the median total time for completing spirometry, giving feedback and the standard brief advice to quit was 5 minutes (Chapter 5.2.6). Smokers in both studies received an anti-smoking booklet to take home and neither was offered pharmacological treatment. The availability of nicotine replacement products over-the-counter was similar in my study and the Polish study.

The cohort of smokers in this study with OLF had less severe obstruction than smokers included in the study of Bednarek et. al., in which only 22% of smokers with OLF were classified with mild obstruction (FEV1 > 80% predicted) compared to 55% in my study. A higher proportion (21%) of smokers with OLF in that study were classified with severe obstruction (FEV1 <50 % predicted), the group for which cessation rates were highest, compared to 6% in my study (193).

In contrast, a Belgian study in primary care selected smokers with higher motivation who were already in the preparation stage. Of 1,206 smokers who had spirometry in primary care around 27% were in Preparation or Action, and only 221 smokers in these stages were actively followed up and assisted with smoking cessation (318). Among this more motivated sample of smokers, at six months the self-reported quit rate was 29% based on 87% successful follow-up rate. Participants were allocated to

spirometry by GPs on the basis of tossing a coin. Only 89 smokers had spirometry and were given feedback on the result. In this small sample, no significant difference in smoking cessation rate was found between those found to have airflow obstruction defined as FEV1/FVC <0.7 (33%) or normal lung function (37%) at six months. However the study protocol required GPs to prescribe nicotine replacement therapy and/or bupropion to all smokers recruited. At least 51% definitely received a prescription and only 12% did not receive one, compared to around 90% of smokers in this study with no record of assistance with cessation recorded by their GP. Assuming no cessation in smokers in earlier stages of change who were not followed up, the quit rate in the study of Buffels et al was 5.3% for the whole population of smokers that underwent spirometry (318), a level very similar to the quit rate in this study of non-selected smokers. Although the general practice setting of the study by Buffels et al was similar to this study, no data were collected on participants' attitudes to general health and the effects of smoking on their health. Overall, the study of Buffels et al is difficult to evaluate because of its complexity and number of potential confounding influences.

The effect of spirometry feedback has also been studied in smokers who also, as in the Polish study, responded positively to an invitation for spirometry screening in primary care practices in Sweden (44). Spirometry was followed by 5-8 minutes of feedback and advice on smoking cessation by a trained nurse. Specific advice on nicotine replacement products (available over the counter) and bupropion (prescription provided by mail) was also given. The 12-month quit rate among 119 smokers with airflow obstruction (FEV1/FVC<88% predicted [males] <89% predicted [females]) was 18% compared to 5% for 161 smokers with normal lung function (194). Being positive volunteers, these smokers (estimated at 10% of the population of smokers in the city) were likely to have been more motivated to stop than non-responders. Although the feedback intervention was given by a nurse and did not involve the GP as in this study, the counselling was more intensive and included specific assistance and provision of a prescription for medication, thus resulting in a complex and mixed intervention. Apart from the brief stop smoking message from the trained nurse, smokers in my study were encouraged to consult their GP for more advice. Examination of records showed that around 80% had no additional GP advice recorded with no difference between feedback groups. In this study an even lower proportion, around 10%, received ancillary assistance with cessation from a GP, although this does not include those who may have bought

nicotine replacement products over the counter. However, the proportions with no assistance recorded did not differ between the OLF and NLF groups. In both Australia and Sweden a prescription is required for bupropion. In my study around 3% of both the OLF and NLF groups received a prescription for bupropion and in the Swedish study 5% of the airflow obstruction group and 1% of the normal lung function group received a prescription. However, recorded use of nicotine replacement products was higher in that study (in 29% of the airflow obstruction group and in 15% of the group without) than in my study (1% OLF and 2% NLF) (194).

Thus the more intensive counselling and pharmacological support received in the Swedish study may also have contributed to the higher quit rate compared to my study. Thus for a number of reasons my study is not truly comparable to the other small number of somewhat similar studies in the literature.

However, in the NLF feedback group in this study, the rate of smoking cessation of 4.2% is remarkably similar to that found in the pooled result of 4% from a meta-analysis of seventeen randomised studies for a similar verbal 'stop smoking' message supplemented by provision of some sort of printed material (143).

Baseline factors found to be significant predictors of smoking cessation in this study were similar to those found in other studies; lower nicotine dependence and previous quit attempt (193,344,345), later stage of readiness to quit (345), lower smoking exposure (193) and higher self-efficacy expectations for quitting (179).

7.5.9 Attempts to quit

Attempts to quit smoking were not reported in other spirometry feedback studies in primary care. Over 30% of the smokers in this study reported having made an attempt lasting at least 24 hours in a three month period following spirometry. Having made a quit attempt is a predictor for sustained cessation with both minimal and more intensive interventions (344). An interesting finding in this study is that around 10% in both categories of spirometry feedback reported making four or more attempts to quit by three month follow up. If these smokers were identified better in general practice, they could be offered more intensive assistance with pharmacotherapy, which would increase their chances of achieving and maintaining cessation (144). My study emphasises the lost opportunities in general practice with the current reactive style of clinical management (346).

7.5.10 Follow up assistance by GPs

The approach to smoking cessation recommended in clinical practice guidelines is the 5-A's approach: Ask, Advise, Assess, Assist, Arrange (140). Examination of practice records in a sub-sample in this study indicated that there was a low frequency of recording of smoking status, advising and giving assistance to patients with quitting. While records may not always reflect the actual frequency of advice given or some types of assistance, such as making a plan for quitting and problem solving, both the recording of current smoking status and the recorded use of pharmacotherapy to support cessation were low, suggesting that practices were not adhering to the recommendations in guidelines and this is at odds with the qualitative findings in which GPs placed a high value on identifying smokers and promoting smoking cessation. Changing the behaviour of GPs to increase implementation of guidelines in practice is difficult (347) and measures to increase compliance with guidelines for processes of care have variable effects using a variety of interventions (348). One randomised study in the Netherlands using small group educational sessions and peer review on guidelines for asthma and COPD found only a small effect on provision of smoking cessation advice that was not significantly different from the control group (349). Another study in Belgium using a multi-component intervention including education, feedback and peer review did not find a significant effect on provision of smoking cessation advice assessed by patient questionnaire (350). The rate of provision were higher in that study than measured in patient records in the study reported in this thesis and may reflect under-recording by GPs (300).

7.5.11 Study strengths and limitations

The high participation rate (98%) amongst eligible smokers in practices and the high rate of successful follow-up (91%) were strengths of this study in addition to its "real life" setting. As the participants in my study were recruited without selection for motivation, which is known to increase the success rate for quitting (144), the results are likely to be generalisable to most primary care settings.

A potential limitation in this study was the use of self reported data for follow-up without validation (183). However, data from the Lung Health Study found only a small bias towards over reporting of abstinence for self-report compared to biochemical validation of status (267) and the effect size for knowing the status of lung function was similar to the validated effect size in the study of Bednarek et al

(193). A review of outcome assessment methods in smoking cessation studies concluded that false reporting of smoking cessation is unlikely in a low-intensity intervention study such as in this study. Thus, there was very little discrepancy comparing self-report with rates based on biochemical validation for studies of untreated volunteers (2%) or low-risk medical patients in intervention studies (3%)(183).

Another limitation was the relatively small size of the cohort, which may be the cause of Type II errors in the effect of feedback on spirometry on positive stage shift and smoking cessation. As indicated in 6.2.1, the size of the cohort was less than anticipated due to low recruitment in one practice that had a lower proportion of patients that were current smokers. Recruitment of smokers could be improved if accurate practice demographics were available during study design. Using the actual difference we found between NLF and OLF feedback groups, a sample size of 1,400 participants would have been required to have power of 80% to show a significant effect for forward shift in the Transtheoretical Model and 2,600 participants to show a significant result for sustained cessation. However, given the novel components in my study that knowledge was not available at the time of design and commissioning of the study. Given the resources available, it would not have been possible to undertake such a large study in this time scale. However, what has been achieved and learned is substantial, and the ability with this information on which to power future studies, is a major advance.

7.5.12 Conclusions

This study showed no association between receiving a report of normal lung function in smokers and backward shift in stage of quitting. The lack of a major adverse effect on motivation in smokers with normal lung function is perhaps the major and most definite outcome of the study. The implications of this study are reassuring for primary care spirometry practice and should remove one of the potential barriers to implementation of guidelines in Australia and elsewhere (3,10,15,54,287).

The association between receiving a report of lung damage due to smoking and forward shift in stage of quitting was not statistically significant, although the study was affected by lack of power to detect an effect and a larger study is required to test this.

The study indicated that when providing feedback on spirometry in primary care it may be necessary to take into account the existing attitudes and beliefs of individual

smokers. The message should be personalised. Smokers whose spirometry results are adverse and who are already pessimistic about their lung health need particular attention from GPs and care in the use of spirometry, as reinforcement of their pessimism may well have negative effects. An emphasis could be given to the value of quitting for other health benefits in addition to prevention of further lung damage, but that too needs testing.

Chapter 8

Summary and conclusions

8.1 Evidence for guideline recommendations

The need to improve the diagnosis of COPD in the community was one of the underlying imperatives of the Australian COPDX guidelines published in 2003 which aimed “to effect changes in clinical practices based on sound evidence” (3). A critical examination of practicalities involved in the recommendation to consider COPD in smokers and ex-smokers aged over 35 contained in these guidelines was the basis for the research studies presented in this thesis.

Over 35 years ago, Cochrane and Holland made the point that using screening tests in medical practice could not be justified only on the albeit reasonable hope that by uncovering the “iceberg” of disease, earlier diagnosis would somehow make the therapies then available more efficient (82). They said that screening should also be ethical, cost effective and most fundamentally, the effectiveness of screening should be objectively tested, ideally in randomised trials. These principles were developed into seven criteria that should be met in any screening programme (351):

1. Has the effectiveness of the programme been demonstrated in a randomised trial?
2. Are efficacious treatments available for those identified?
3. Does the burden of suffering warrant screening?
4. Is there a good screening test?
5. Does the programme reach those who could benefit most?
6. Can the health system cope with the programme?
7. Do persons with positive screenings comply with advice and interventions?

If these criteria are applied to the use of spirometry for detection of COPD, the consensus of expert opinion (93) and systematic review of the evidence (53) is that while general population screening is not justified, the case may be stronger for high-risk population screening (especially of smokers who do not see a doctor in primary care for long periods) (352) and focused case finding in primary care (108).

Case finding, as recommended in the COPDX guidelines (3), is based on the use of spirometry “to demonstrate airflow limitation which is not fully reversible” in the at-risk population. Although there is good evidence that spirometry is necessary to make a diagnosis of COPD (53), the COPDX guideline authors acknowledged the lack of high-level evidence to substantiate the recommendation for the diagnosis of

COPD to be sought (and therefore the need to perform spirometry) in all smokers and ex-smokers older than 35 years in primary care.
Even with the explosion in production of clinical practice guidelines during the past three decades, changing clinical practice has been shown to be difficult and there is a lack of consensus on how to achieve positive change. Evidence-based medicine needs to be complemented by evidence-based interpretation (115)(347).
Thus, the aim of the studies presented in this thesis was to test the assumptions that spirometry would be taken up into general practice for the diagnosis of COPD and that it would be beneficial, easily assimilated into practices and have no negative outcomes. The following sections present a summary of how these aims were met and recommendations for some changes in areas of health service delivery that may need to be implemented in the light of the findings.

8.2 Assessment of spirometer device

An essential requirement for optimal spirometry was to choose and test a suitable device for use in practices in primary care, an issue not addressed in the COPDX guidelines. The EasyOne spirometer, selected on the basis of its novel ultrasonic technology, was shown to be reliable and to maintain its accuracy over twelve months while in regular use by operators who were trained but non-specialists. This confirmed the particular suitability of the EasyOne for spirometry performed in primary care.

8.3 Preliminary study

Interaction with clinical practice in primary care commenced with a qualitative assessment of the attitudes of GPs and patients to COPD, and gathering of background information on how COPD presents and is managed in practices. This revealed that most cases of recognised COPD were diagnosed late- usually following admission to hospital with an exacerbation. In around half of those that had been diagnosed in general practice, the diagnosis of COPD was not preceded by spirometry and even then it was unusual for the spirometry to have been done in the practice. No cases of recognised COPD were mild at the time of diagnosis but all had already been symptomatic over long periods and frequently multiple typical symptoms and exacerbations had been documented. The narrative accounts of patients with a diagnosis of COPD confirmed high levels of respiratory and

psychological morbidity, and illustrated how the delayed diagnosis caused frustration for patients. The insights gained directly from GPs on their attitudes to COPD are unique and explain much of the dysfunction in clinical practice just outlined. They give insights that are highly pertinent to attempts to change clinical practice. COPD was acknowledged by both GPs and patients to be a progressive and disabling disease, and they described it using terms such as “palliative care”, “a horrible way to spend the last 10 or 15 years of your life”, “incurable” and “all down hill from here”.

Discussions with GPs showed that the delay in diagnosis, unusually in medical practice as applied to most diseases, even when the prognosis is as poor as in lung cancer (247), appeared to be intentional and not a systems issue. Although GPs did not perceive delayed diagnosis to be associated with any adverse consequences it does in fact represent a lost opportunity for intervention, especially through promotion of smoking cessation and optimisation of effective therapy now available to relieve symptoms and prevent exacerbations (287).

Lack of spirometry was also clearly a potential added or contributory reason for GPs not making the diagnosis of COPD, and a number of possible barriers to performing spirometry emerged. GPs were generally short of time, they lacked spirometry equipment and training in performance and interpretation, they were deterred by cost considerations for themselves and for patients, and they were concerned that normal spirometry results in smokers would make them less motivated to quit smoking.

8.4 Intervention study

Following the preliminary investigation and using the insights gained, a controlled study was designed to compare and contrast different practical approaches to enhancing the diagnosis of milder cases of COPD: a trained nurse model (TN) of opportunistic spirometry sessions and the model of usual care (UC) in practices provided with a spirometer, training in use and interpretation and reimbursement for testing.

Two hypotheses underlying the intervention study are considered in the next sections in relation to the findings that emerged.

8.4.1 Hypothesis 1

That in comparison with usual care, a model using trained nurses will be effective in increasing the frequency and quality of spirometry performed on smokers and ex-smokers in general practice.

A significantly greater number of patients belonging to the group at risk of COPD underwent spirometry in the TN model than in the UC model. In the TN model, the proportion of the population at risk that visited the practice and was tested with spirometry during a six-month period was significantly greater than the proportion tested from the same at risk population who were seen by GPs in the UC model. Furthermore, spirometry performed in the TN model was clearly of significantly better quality than in the UC model. It needs to be emphasised that achieving a good quality result is paramount in spirometry for accurate clinical interpretation. Interview feedback from GPs indicated they agreed that it is essential to have a trained skilled operator with dedicated time and ability to perform sufficient spirometry to achieve and maintain high quality test results. It became clear that, performing spirometry is not a role that most GPs will undertake themselves. As this study found, performing spirometry is a role potentially well suited to practice nurses who are working in an increasing proportion of Australian general practices (353). Although practice nurses currently assist GPs to treat illness and injury through more traditional nursing tasks (354) my study showed that spirometry training delivered in a short course (of only 2 hours) was effective in achieving competency, that grew as more testing was undertaken. Although data on Medicare reimbursement for spirometry indicate that the current frequency of testing in an average practice is almost certainly too low to maintain a good level of expertise, this could perhaps be increased sufficiently with spirometry performed for asthma management as part of the 3+ asthma visit (355) combined with a service directed to diagnosis and management in COPD. However, this is unlikely to happen without increasing the reimbursement for spirometry with bronchodilator reversibility through Medicare, to a more realistic level to cover the time and equipment required, and also introducing reimbursement for a single completed test, the latter being especially important in the context of smoking related COPD. However, as my study demonstrates, a trained nurse visiting practices to offer regular spirometry sessions is very effective in delivering good quality results, though this model too would rely on spirometry attracting realistic reimbursement through Medicare to make it viable for practices.

8.4.2 Hypothesis 2

Performing spirometry on smokers and ex-smokers aged over 35 in general practice, as specified in COPDX guidelines will facilitate early identification of COPD.

Spirometry was shown to be effective as a pure case-finding exercise, particularly using the TN model. In the UC model, fewer of those tested (around 35%) did not report or have a respiratory diagnosis already recorded than in the TN model, where nearly 75% were found to be previously unrecognised. Those identified with airflow obstruction (defined by the accepted criterion of FEV1/FVC ratio less than 0.7) in the TN model were more likely to have mild obstruction compared to in the UC model. Thus, the TN model was considerably more effective in identifying COPD at an earlier stage. However, this was not matched by a corresponding increase in the recording of new diagnoses of COPD in patient records, markedly undermining the potential cost effectiveness of the TN model. Thus, the study identified deficiencies in practice systems, with lack of GP review of test results, lack of dedicated spirometry follow up with the patient and uncertainty over interpretation of test results being significant factors that contributed to under-recognition of COPD.

It is probable that a combination of strategies will be required to change GP behaviour and facilitate better use of spirometry results for diagnosing COPD. A comparison of qualitative data from the preliminary study with data collected about two years later during the intervention study indicated a shift in GP attitudes. The earlier attitude in which GPs avoided making a diagnosis in primary care was changing and evolving to a consideration of how the diagnosis could contribute to enhancing patient self-management overall. This shift is subtle but may indicate a "Hawthorne effect" (356) with change in attitude and practice by GPs, being themselves a very result of becoming familiar with an optimal spirometry delivery model.

8.5 Spirometry and motivation for smoking cessation

While conducting the comparison of spirometry delivery models the opportunity was taken to observe how contrasting spirometric feedback to smokers affect preparedness for quitting smoking, and especially to evaluate possible negative effects, as those were a particular cause of concern for GPs and a barrier to take-up of spirometry testing for COPD diagnosis.

8.5.1 Hypothesis 3

Identification of airflow limitation in smokers will act as an incentive for smoking cessation.

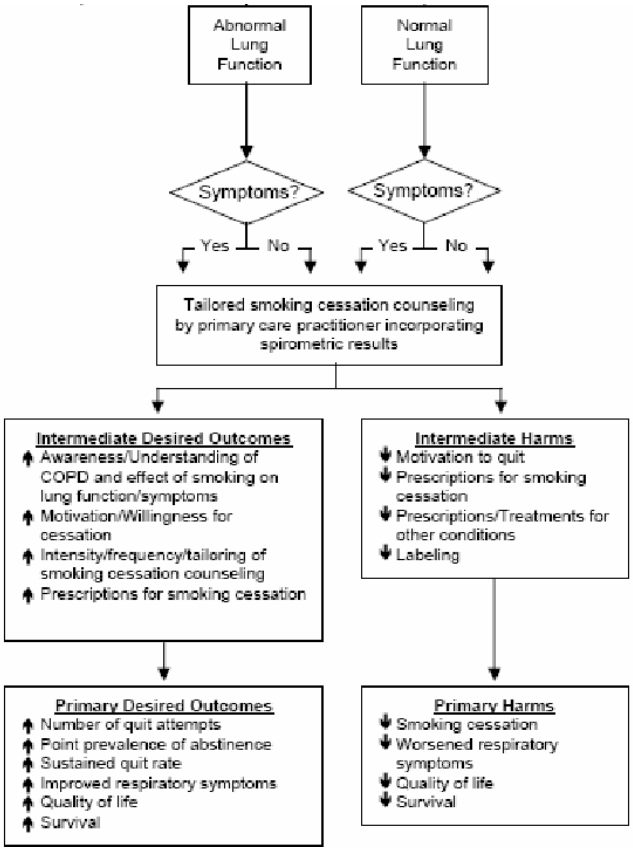
I found using analysis of the Transtheoretical Model stages of change, that there was no negative effect on motivation to quit smoking for smokers informed of the absence of lung damage from smoking after spirometry i.e. normal spirometry. Tobacco addiction remains a serious public health issue in Australia as in other countries. Encouraging all smokers to quit, preferably before lung damage has occurred, must become an important priority for GPs, who will now find the absence of a negative effect on motivation by a normal spirometry result reassuring.

The additional positive benefit of increasing motivation and preparedness to quit smoking in smokers informed of the presence of lung damage (although not statistically significant this study sample size) is likely to increase subsequent cessation if this system is applied on a larger community level. However the personality and attitudes of the individual smoker need to be taken into account. This study found an effect on smokers with pre-existing poor perceptions of lung health that communicating a result confirming abnormal spirometry (reflecting lung damage from smoking) made this group move backwards in preparedness to quit. Thus, care must be taken not to reinforce a nihilistic attitude to quitting in such individuals. That GPs are able to finesse the message to smokers in practice, and are already doing so, was confirmed by the qualitative results and should be encouraged in future clinical practice.

The report on spirometry prepared for the U.S. Department of Health and Human Services in 2005 listed desired outcomes and potential harms from the use of spirometry in current smokers and the need for tailoring of smoking cessation counselling (Figure 8.1)(53).

Figure 8.1 Potential role for, and outcomes from, spirometry used as a motivational tool for smoking cessation

Reproduced from:
Wilt T, Niewoehner D, Kim C-B, Kane R, Linabery A, Tacklind J, et al.
Use of Spirometry for Case Finding, Diagnosis, and Management of Chronic Obstructive Pulmonary Disease (COPD).
Rockville, MD: Agency for Healthcare Research and Quality; 2005 September 2005. Report No.: Publication No. 05-E017-2



My study confirms there are no intermediate harms to motivation or decrease in prescriptions for smoking cessation associated with a report of normal lung function, and indeed shows that there is evidence for increased motivation with a report of abnormal lung function in general. There was also evidence for the need to tailor smoking cessation counselling, especially for those pessimistic about their lung health.

8.6 Recommendations

Factors identified that limited full benefit from an intervention to increase case finding with increased spirometry testing through the Trained Nurse model need to be addressed effectively, with subsequent frequency of COPD diagnosis being monitored and audited. Further, I would suggest that a controlled study should

compare patient recall for dedicated spirometry follow up with the GP to specifically discuss the result, record and communicate a diagnosis, and agree on a management plan (including assistance with smoking cessation) against usual care.

Use of existing and new methods to support and assist GPs in spirometry interpretation, such as an Australian web-based diagnostic algorithm for COPD and asthma (http://www.dmac.adelaide.edu.au/copd/index.htm# linked to the COPDX web site http://www.copdx.org.au/checklist/index.asp) and links with special interest GPs should also be studied in controlled trials.

One of the key recommendations contained in the funding submission “A National Approach to COPD in Australia” made by the ALF and TSANZ to the Australian Government in 2006 (357) was for an increase in the Medicare Benefits Schedule rebate for doctors to perform spirometry from $15.10 to $30.62 (85% of $36.00 fee), based on costs for a practice nurse using the EasyOne spirometer. The government should be encouraged to implement this recommendation and also introduce a realistic rebate for single spirometry without the need for repeat testing post-bronchodilator. I feel that removal of the current practical disincentive and an adequate financial incentive for spirometry are essential for adoption of any model of spirometry delivery in primary care.

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Appendices

Appendix 1a: Pilot Study Patient Information and consent.

INFORMATION SHEET

Title of Research Project

A pilot audit of general practitioners' diagnosis and management of chronic obstructive pulmonary disease

Chief Investigators

Professor Peter Mudge Professor Haydn Walters

Other Investigators

Dr Julia Walters Dr Emily Hansen

Introduction

You are invited to take part in this research project. This information sheet contains detailed information about the research project. Its purpose is to explain to you all the procedures involved in the project before you decide whether or not to take part in it.

Purpose of the study

We are a team of researchers from the University of Tasmania. Through our research we hope to find out more about what it is like to have chronic obstructive pulmonary disease. Chronic obstructive pulmonary disease (COPD) is a disease of the airways that makes people feel breathless, have cough and frequently produce sputum. It tends to occur in middle aged/elderly patients who have a history of cigarette smoking. In this research project we want to find out how COPD is affecting peoples' lives in Australia and to investigate how well their current treatment and management practices are working. We are running this research project out of the Hopkins Street Clinic in Moonah.

Why you can help

We are inviting you to participate because you attend the Hopkins Street Clinic and your general practitioner has previously diagnosed you with COPD. Your general practitioner is associated with this research project and has provided us with your name and address. Participation in the study is entirely voluntary and you would be able to withdraw from the study at any time. Your medical treatment from your GP will not be affected by either participation or withdrawal from the study.

What your participation would involve

If you choose to participate in the research, you will be invited to attend the Hopkins Street Clinic where you will meet with a research nurse who will talk through the project and answer any questions you may have. You will then be invited to sign a consent form. By signing the consent form you will not alter your legal rights, but you indicate that you understand the information and that you give your consent to participate in the research project. You will be given a copy of this form and the information sheet to keep. Even if you participate in some sections of the project you may decline to participate in any other section of the project.

The research nurse will then ask you detailed questions about your respiratory health using three questionnaires. She will also carry out breathing tests and skin tests to identify allergies. Any information arising from these tests will be given to your usual general practitioner.

The breathing tests are not painful and involve blowing into a machine, both before and after an inhaled dose of salbutamol (ventolin), which is a medicine to open up your airways. Ventolin is very commonly used for relief of symptoms in COPD and asthma.

The skin test for allergies involves placing droplets of allergens (eg house dust mite) on your forearm and gently pricking the skin. If you are allergic to a substance a small itchy lump will develop, but a soothing cream will be applied and the skin should rapidly return to normal..

In addition to your visit, a doctor will review your case notes to confirm the date your breathing condition was diagnosed, what tests were performed and what medications you take.

Confidentiality and Results

Any information you give us will be confidential. No findings which could identify you individually will be published. Your anonymity is assured by our procedures in which information is identified by a code number and only the combined results of all participants will be published. All information will be kept under secure conditions which only the investigators and nominated research staff can access. All information will be stored securely for seven years as required by University regulations, and then destroyed. Any medical results arising from the consultation will be given to your usual general practitioner who will discuss them with you if you want.

Ethics

This project has received approval from The Southern Tasmania Health and Medical Human research Ethics Committee. If you have any concerns of an ethical nature or

complaints about the manner in which the project is conducted you may contact the Chair of the Southern Tasmania Health and Medical HREC (Dr Helen McArdle - 6226 2763) or the Executive Officer (MsAmanda Mcaully - 6226 2763)

Contact Persons

If you would like more information about the study please contact:

Professor Peter Mudge 6226 4731

Professor Haydn Walters 6226 4870

Dr Julia Walters 6226 4870

Dr Emily Hansen 6226 4769

Thank you for your assistance with our research.

Professor Haydn Walters Professor Peter Mudge

Dr Julia Walters Dr Emily Hansen

STATEMENT OF INFORMED CONSENT (To be signed at the clinic by the subject and the research nurse)

Title of project: A pilot audit of general practitioners' diagnosis and management of chronic obstructive pulmonary disease

Statement by research participant

1. I have read and understood the 'Information Sheet' for this study.
2. The nature and possible effects of the study have been explained to me.
3. I understand that by participating in the study I am willing to (please tick):
    a. have breathing tests
    b. have skin testing for allergies
    c. complete respiratory questionnaires administered by a research nurse
    d. have my medical notes reviewed by a doctor
4. I understand that all research information will be treated as confidential.
5. Any questions that I have asked have been answered to my satisfaction.
6. I agree that research information gathered for the study may be published provided that I cannot be identified as a subject,
7. I agree to participate in this investigation and understand that I may withdraw at any time without prejudice. I understand that my ongoing medical care will not be affected by withdrawal from this project.

Name of participant

Signature of participant Date

Statement by the Investigator

I have explained this project and the implications of participation in it to this volunteer and I believe that the consent is informed and that he/she understands the implications of participation.

Name of investigator

Signature of investigator Date

Signature of witness Date

Appendix 1b: Pilot Study GP Information and consent.

INFORMATION SHEET FOR GENERAL PRACTITIONERS

Title of Research Project

A pilot audit of general practitioners' diagnosis and management of chronic obstructive pulmonary disease

Chief Investigators

Professor Peter Mudge, Professor Haydn Walters

Other Investigators

Dr Julia Walters, Dr Emily Hansen

A research project investigating the management and diagnosis of COPD is running at the……..Practice. This research is a pilot for a larger study we wish to initiate investigating the management of COPD and 'chronic asthma' in the community. The project has a number of interrelated aims.

Aim 1. To investigate the management of COPD in a general practice setting and at the hospital/community interface and to compare this with national standard guideline

Aim 2. To evaluate the lung function and morbidity levels of COPD patients in general practice

Aim 3. To conduct an impact assessment of COPD on patients in general practice and to investigate doctor/patient understandings of COPD

Aim 4. To trial the running of this research project in one general practice in order to establish the viability of a larger scale Tasmanian study of COPD suitable for NHMRC (or similar) funding.

The names of fifty individuals with a diagnosis of COPD who are over the age of fifty and less than seventy have been randomly selected from the computer records of the… … … … … … Clinic. Each of these patients will be contacted and invited to participate in the research project. Their participation would involve:

- Two interviews about their understandings of the condition

- Collecting information about the health and respiratory history of these patients using standardized questionnaires and lung function testing.

- Reviewing their case notes to collect information about date of original diagnosis (if available), medication history and evidence of any previous lung function testing.

We would also like to speak with the doctors who work at……about COPD and what it is like to treat patients with COPD. This would involve an informal, tape recorded interview with a member of the research team, Dr Emily Hansen. Emily has a background in medical sociology and a strong interest in medical practice. She is currently working with Peter Mudge in the Discipline of General Practice at the university.

The location, length of time and topics discussed at the interview would be extremely flexible. All information collected during the interview would be confidential. A sample of interview questions is attached to this information sheet.. You will be contacted by either Emily or Peter Mudge and asked if you would like to participate in an interview.

Any information you give us will be confidential. No findings which could identify you individually will be published. Your anonymity is assured by our procedures in which information is identified by a code number and only the combined results of all participants will be published. All information will be kept under secure conditions which only the investigators and nominated research staff can access. All information will be stored securely for seven years as required by University regulations, and then destroyed. Any medical results arising from the consultation will be given to your usual general practitioner who will discuss them with you if you want.

This project has received approval from The Southern Tasmania Health and Medical Human research Ethics Committee. If you have any concerns of an ethical nature or complaints about the manner in which the project is conducted you may contact the Chair of the Southern Tasmania Health and Medical HREC (Dr Helen McArdle - 62228430) or the Executive Officer (MsAmanda Mcaully -62262763)

If you would like more information about the study please contact one of the researchers:

Professor Peter Mudge	6226 4731
Professor Haydn Walters	6226 4870
Dr Julia Walters	6226 4870
Dr Emily Hansen	6226 4769

Thank you for your assistance with our research.

Professor Haydn Walters
Dr Julia Walters

Professor Peter Mudge
Dr Emily Hansen

STATEMENT OF INFORMED CONSENT TO BE INTERVIEWED (To be signed at the interview by the interviewee and the interviewer)

Title of project: A pilot audit of general practitioners' diagnosis and management of chronic obstructive pulmonary disease

Statement by interviewee

1. I have read and understood the 'Information Sheet' for this study.
2. The procedure for this interview has been explained to me.
3. I understand that all information collected during this interview will be treated as confidential.
4. Any questions that I have asked have been answered to my satisfaction.
5. I agree that research information gathered during this interview may be published provided that I cannot be identified as a research participant.
6. I understand that I can ask for the interview to be stopped at any stage during our discussion and for any tape recordings or written notes to be destroyed.
7. I agree to participate in this interview and understand that I may withdraw at any time.

Name of participant .....

Signature of participant ..... Date

Statement by the Investigator

I have explained the details of the interview and the implications of participation in it to this volunteer and I believe that the consent is informed and that he/she understands the implications of participation.

Name of investigator .....

Signature of investigator ..... Date

Appendix 2a: Invitation for practices to participate in a spirometry study

Chronic Obstructive Pulmonary Disease in the Community

In 2002 we recruited some practices to participate in a study on Action Plans in the management of acute exacerbations of COPD. This article briefly reviews the results of the study and asks for expressions of interest in participating in our next study, planned to commence in late 2004.

Our next study plans to examine the use of spirometry in general practice, looking at different models of implementation, its effect on smoking cessation and the impact on diagnosis and management of COPD. We are hoping to recruit 8 general practices for the study that will run for 1 year. Each practice will be provided with a spirometer for use in the practice for 6 months (usual practice arm) and a trained nurse to run spirometry clinics for 6 months (trained nurse arm). General practitioners involved in the study will be offered a 2-hour workshop on performing and interpreting spirometry, asked to involve practice staff in distributing self-administered questionnaires to measure outcomes and invited to participate in focus groups to discuss the two models. If you are interested in participating in the study please contact Richard Wood-Baker (Phone: 0438 213 113, Email: Richard.WoodBaker@utas.edu.au)

Appendix 2b: Information for practices

Thank you for your interest in this study. It will be jointly run by the Departments of General Practice and Medicine and will involve eight practices in southern Tasmania. The study targets people who are smokers or ex-smokers aged over 35 years for measurement of their lung function by spirometry.

Organisation of the Study

It will start in late 2004 and run for twelve months, divided into two randomly allocated six month periods. Each practice will have one period in which a trained nurse spends at least two 3 hour sessions per week performing simple spirometry, without bronchodilator reversibility, opportunistically in the targeted patients attending the practice for any reason.

During the other period, an easy-to-use hand-held spirometer will be provided to the practice for use by the GPs (and practice nurses if you like) for lung function to be measured in the same target group.

What is required from the practice

During the time the trained nurse is visiting, the receptionist will be asked to offer a questionnaire to any patient visiting the practice over 35 years old, receive completed questionnaires and give them to the visiting nurse then, or at her next attendance. We would also put up posters encouraging smokers and ex-smokers over this age to ask for a lung function test.

The trained nurse will require space to perform spirometry, she will explain the study and get consent from patients willing to take part and we will follow them up with questionnaires immediately after spirometry and three months later. Some patients will be invited to an interview to explore the effect of spirometry on their perception of risks of smoking

You will receive the results of spirometry by fax within 48 hours. We would like to review the records of patients who consent, to extract data on respiratory diagnoses and medications.

When the practice has a spirometer, any patient in the target group who has lung function measured should be given a one-page questionnaire and information sheet and asked to give consent for their records to be examined for respiratory diagnoses. Results of spirometry tests performed will be downloaded for analysis by researchers and a payment of $10 made for each test on a target patient.

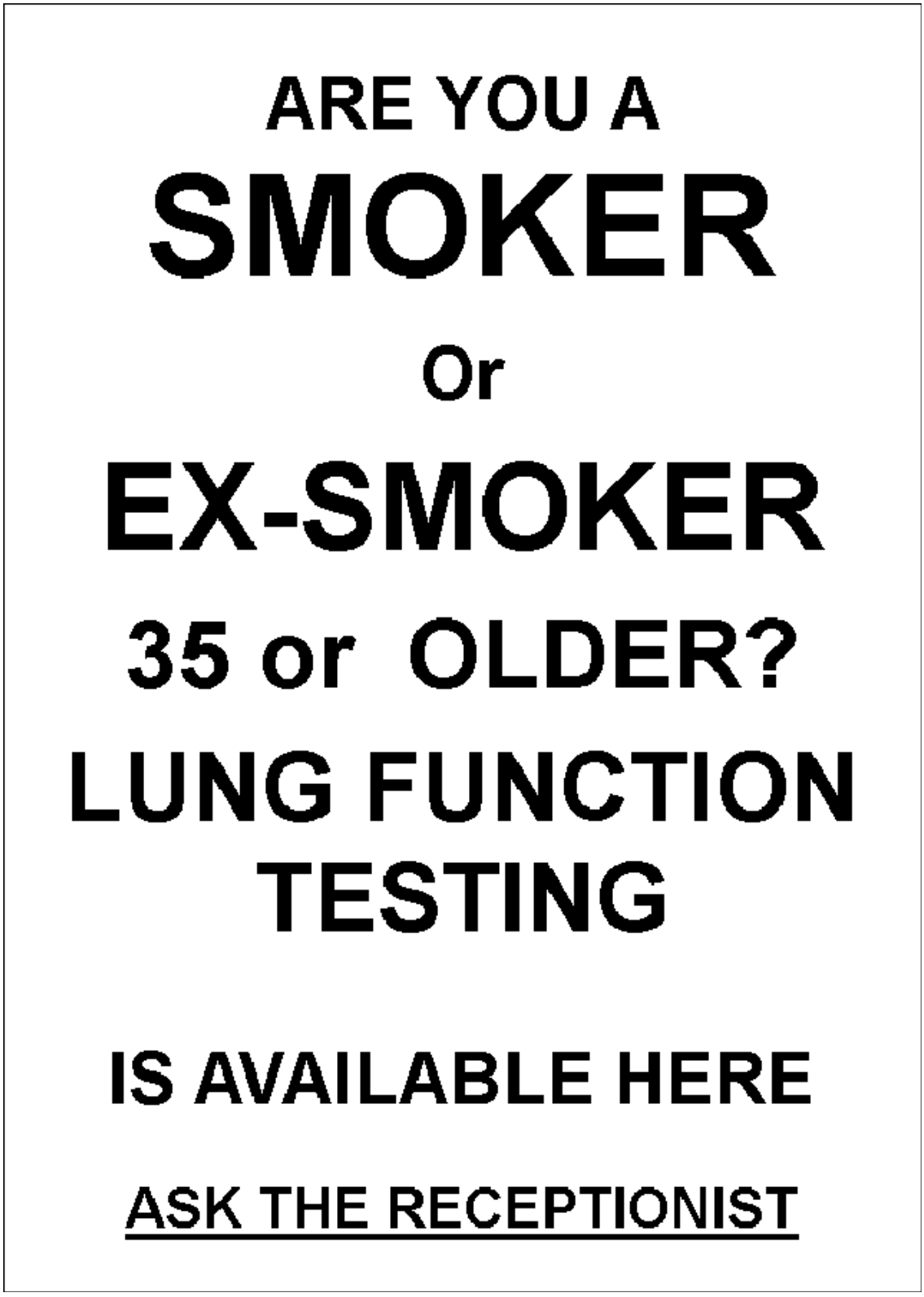
What is required before taking part

An educational session, for which CME points have been applied, will be held for GPs participating in the study. This 3 hour session will cover spirometry, interpretation of results and the diagnosis of COPD.

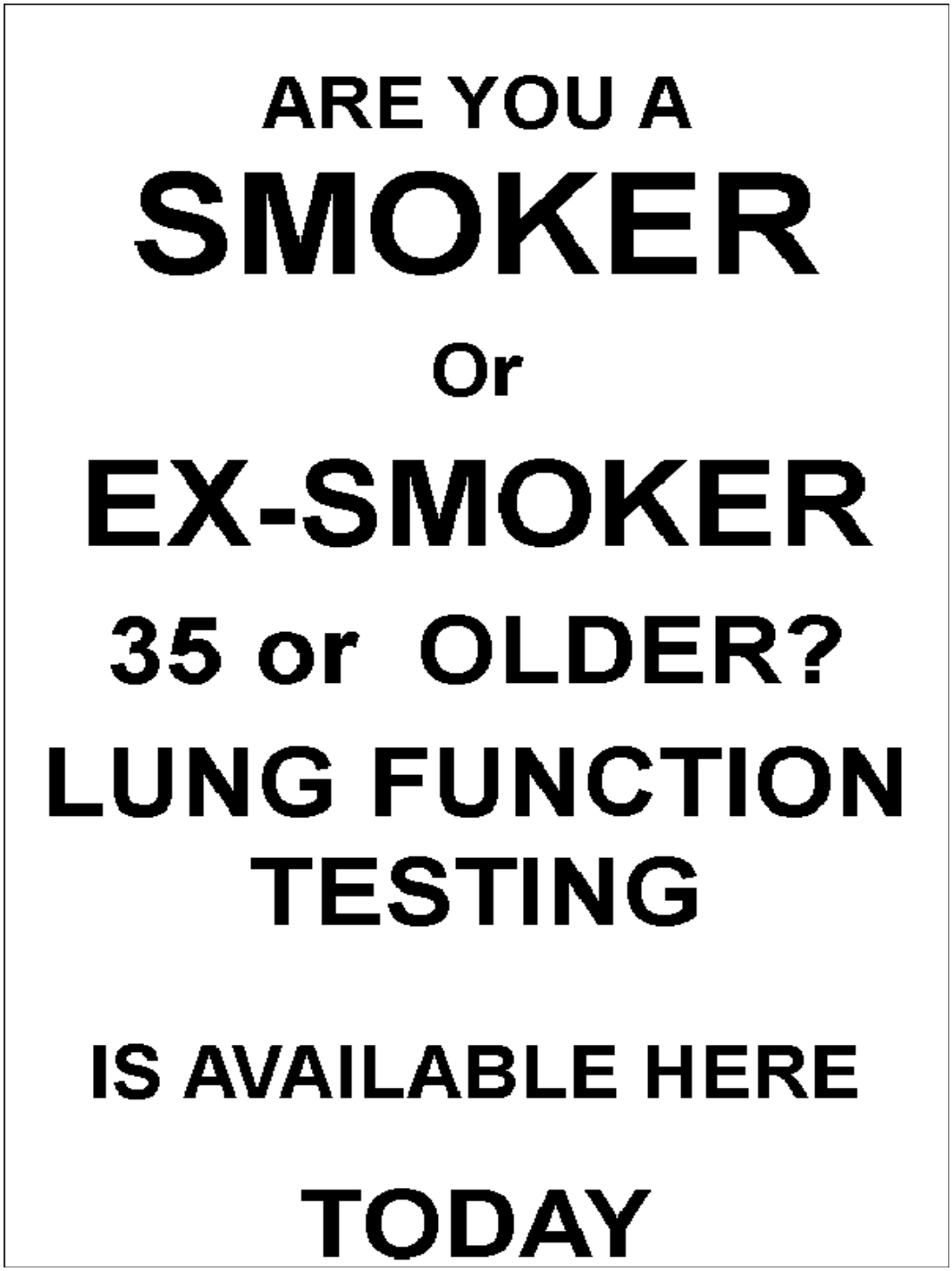
Outcomes of the study

Uptake of spirometry in at-risk patients, diagnosis of COPD, effect of the spirometry result on patients' decisions to continue to smoke. Quit Tasmania packages will be given to all smokers having spirometry.

Appendix 3 Trained nurse model- practice study poster



Appendix 4 Trained nurse model- spirometry session poster



Appendix 5 Trained nurse model- spirometry session receptionist reminder

RECEPTIONISTS
TODAY
Please ask ALL patients who come in

"Have you ever been a smoker? (Now or Ex)
Are you 35 years or over?"

If the answer is YES to BOTH

"Would you take a questionnaire, read it and fill it in while you are waiting and give it back to me"

Appendix 6:
EasyOne Specifications: EasyOne Model 2001 Spirometer

Dimensions: 3.3 x 6.2 x 1.7 inches (83 x 158 x 43 mm)

Weight: 9 ounces (245 g)

Accuracy: Volume: ±2% or 0.050 L, Flow: ±2% or 0.020 L/s, PEF: ±5% or 0.200 L/s, MVV: ±5% or 5 L/min

Resolution: Volume: ≥1 ml/s, Flow: 4 ml/s

Range: Volume: ±12 L, Flow: ±16 L/s

Resistance: approx. 0.3 cm H2O/L/sec

Display: 64 x 160 pixel graphic display

Data Entry: 14-button rubber keypad with tactile feedback

Data Storage: 700 patient memory

Test Types: FVC, FVL, SVC, MVV, Post Medication Comparison

Parameter: FVC test: FVC, FEV1, FEV3, FEV6, FEV1/FVC, FEV1/FEV6, FEV/VC, FEV1var, FEV6var, FVCvar, FEF75, FEF50, FEF25, FEF25-75, PEF, Tzero, BEV, EOTV, PEFT, FET

FVL test: FIVC, PIF, FIF75, FIF50, FIF25

SVC test: VCmax, VCin, VCex, IC, ERV, IRV, VT, Rf

MVV test: MVV, BPM

Mouthpiece: Disposable spirette® breathing tube

Measurement Principle: Ultrasound Transit Time Analysis

Predicted Normals: NHANES III, Knudson 1983, Knudson 1976, Crapo, Morris, Cherniak, ERS (ECCS), Roca (Spain), Forche (Austria), Sapaldia (Switzerland), Berglund, Gulsvik, Hedenström, Asia 1-4, JRS 2001, Gore/Crocket, Pereira Pediatric: Dockery, Hsu, Zapletal, Hibbert

Power: (2) AA batteries

Battery Life: Approximately 400 Tests

Protocol: 8½ x 11’’, in connection with a HP, Canon or Epson printer

Storage / Operating Range: Temperature: -40 to 70 °C 0 to 50 °C

Relative humidity: 10% to 95% 0% to 95%

Ambient pressure: 500 to 1060 hPa 500 to 1060 hPa

Device Compliance: ATS/ERS Standards, CE certificate; CSA certificate; FDA

Equipment Classification: Type BF Equipment, Equipment not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.

Appendix 7: Example of EasyOne spirometer report

easyone(TM) DIAGNOSTIC 2.9
(c)mdd 2000-2004
EasyWare 2. 8. 0. 0
SN 50780

Patient Information

Name	IW
ID	
Age	17 (24.06.1987)
Height	183 cm
Weight	70 kg, BMI 20.9
Gender	MALE
Ethnic	CAUCASIAN
Smoker	NO
Asthma	NO

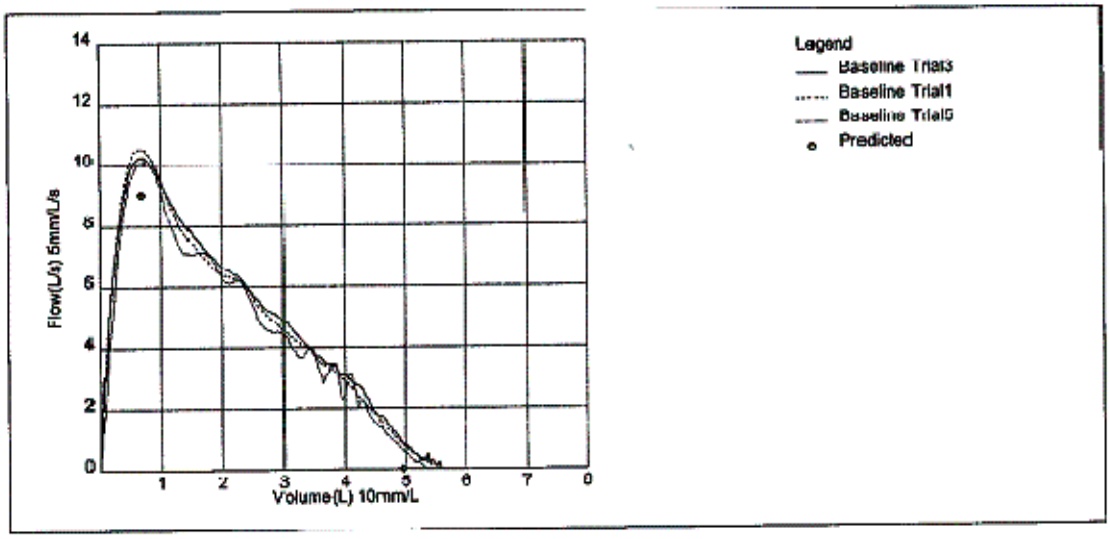
Test Information

Test Date	26.10.04 23:09
Post Time	--:--
Test Mode	DIAGNOSTIC
Interpretation	NLHEP
Predicted Ref	Knudson 76
Value Select	BEST VALUE
Tech ID	1
Automated QC	ON
BTPS (IN/EX)	-.--/ 1.04

Test Results — **Your FEV1 is 108% Predicted**

Parameter	Baseline Best	Trial3	Trial1	Trial5	Pred	%Pred
FVC(L)	5.57	5.57	5.55	5.31	4.97	112
FEV1(L)	4.70	4.70	4.63	4.56	4.37	108
FEV1/FVC	0.84	0.84	0.83	0.86	0.85	99
PEF(L/s)	10.19	10.19	10.47	10.06	9.04	113
MEF25-75(L/s)	4.72	4.72	4.55	4.58	5.46	86
MEF75(L/s)	8.26	8.26	7.97	7.36	-.--	--
MEF50(L/s)	5.22	5.22	5.01	4.77	-.--	--
MEF25(L/s)	2.79	2.79	2.58	2.39	-.--	--
FET(s)	7.99	7.99	6.92	3.70	-.--	--

Baseline: FEV1 Var=0.08L 1.7%; FVC Var=0.02L 0.4%; Session Quality A
Interpretation: Normal Spirometry



Appendix 8: Practice records data extraction form

Investigator			Spirometry result in notes					Patient consent			
Practice			Patient ID		Name						
Paper records used			Electronic records used								
Date spirometry			Date extraction					**> 3mths**			
# consultations 3/12 prior			# consultations 3/12 post					# after 3/12			
Diagnosis in summary	12/12 PRE SPIR	POST			Medications	12/12 PRE SP	POST				
Asthma					SABA						
Chronic bronchitis					LABA						
Emphysema					ICS						
COPD					Anticholinergic						
Interstitial lung dis.					Spiriva						
other					comb ICS/LABA						
					Theophylline						
Recorded smoking status	12/12 PRE	POST			Flu vacc						
Current					Pneum vacc						
Ex-smoker					other						
Non smoker											
Not recorded											
POST SPIROMETRY ONLY											
Smoking cessation advice recorded?					Smoking cessation assistance record?						
Not app		No				Referral					
Yes	Date					Prescribe NRT					
	Date					Prescribe Zyban					
	Date					other					
Repeated spirometry ?					Refer Resp Specialist						
by GP no BD					Refer CXR						
by GP + BD rev					Refer Pulm rehab						
Referred spir			Respiratory symptoms recorded								
no record			Physical activity/limitation recorded								
Time taken			Exacerbation recorded								
	Notes										

Appendix 9: Patient information and consent form for use in TN practices.

Thank you for considering taking part in this study. This tells you about our research project so you can decide whether to take part.

Purpose of the Study

We want to investigate if it is useful to have specially trained nurses in practices measuring lung function (by blowing tests). We want to use these tests to find out which smokers and ex-smokers over 35 years old have chronic obstructive pulmonary disease (emphysema and chronic bronchitis) and find out if the results affect decisions made by smokers about continuing to smoke.

Who can take part

People who are smokers or are ex-smokers aged over 35 years and who are patients of this general practice.

What it involves

Now: The receptionist has given you this information sheet, a consent form and questionnaire. If you have any questions the research nurse will answer them. If you decide to take part you will take the information sheet home with a copy of the consent form.

The questionnaire asks about your smoking history, any lung problems you may have and the medications you are taking.

The research nurse will help you do the breathing test to measure how well you can blow out. It is not painful and takes about 10 minutes. She will briefly explain the results to you and may suggest you make another appointment to discuss the results with your GP.

After, if you are a current smoker: We will give you a second questionnaire to fill in asking about the test and if it had any effect on your feelings about smoking. You can complete it at home and send it back in the reply paid envelope we will give you.

We will contact you in three months and ask you to fill in a third questionnaire about any attempts you have made to give up smoking and how successful these have been.

Optional: A small number of participants will be asked if they would talk to a researcher in greater depth about some of the issues. If selected you will be contacted in

about 4 weeks to arrange an appointment and can chose whether to take part then. This is not affected by your agreement to take part today.

Review of your notes

We would like permission to look at your notes that are kept at the surgery. This is to assess your history of breathing problems (if relevant) and any medications you have been prescribed.

Confidentiality

The information we obtain for the study will remain confidential to the Research Doctors and Nurses. Records are kept locked in the Centre for Clinical Research at the Royal Hobart Hospital. Your anonymity is assured by our use of code numbers and not patient names. No findings which could identify you individually will be published. The information gathered will be stored for seven years as required by the University of Tasmania's regulations and then destroyed.

Freedom to refuse or withdraw

Participation in the study is entirely voluntary, you may decide not to enter or withdraw at any time without giving a reason. Should you decide not to enter or withdraw this will not affect your future medical care in any way.

Contact Person

Please read this information sheet carefully and ask any questions you may have. If you have any queries about the study, or would like to discuss anything further please ask the research nurse on **62267068** or contact **Dr Richard Wood-Baker** on **62227068**.

Ethical Considerations

The Southern Tasmania Health and Medical Human Research Ethics Committee has approved this study. If you have any concerns of an ethical nature or complaints about the manner in which the project is being conducted, you may contact the Ethics Committee

Chair – Dr Helen McArdle on 6222 8430

Executive Officer – Mrs Amanda McAully on 6226 2763

Consent Form

I have read and understood the information sheet for this study.
The nature and possible effects have been explained to me.
I understand that the study involves the following: performing breathing tests and completing questionnaires.
I understand it will involve a consultation with a research nurse at my general practitioner's clinic.
I am agreeable to the researchers viewing my medical records at this practice to extract information on respiratory disease and treatment.
I am agreeable to being contacted in 4 weeks about undergoing an interview as part of the study and will decide on whether to participate further at that time.
I have been informed that the results of the study may not be of any direct benefit to my medical management.
Any questions I have asked have been answered to my satisfaction.
I agree that research data gathered for the study may be published provided that I cannot be identified as a subject.
I agree to participate in this study and understand that I may withdraw at any time without prejudice.

Name of subject:_____

Signature:_____ Date:_____

I have explained this trial/study and the implications of participation in it to this volunteer and I believe that the consent is informed and that he/she understands the implications of participation.

Name of researcher:_____

Signature:_____ Date:_____

Appendix 10: Questionnaire A for use in TN practices

MEASURING YOUR LUNG FUNCTION STUDY

Pag

We are carrying out a study measuring the lung function of people aged over 35 years who have ever smoked. We use a breathing test called SPIROMETRY to measure how well your lungs work. It takes about 5 minutes to do. You have to breathe in deeply and blow all the air out of your lungs quickly at least 3 times after you have had a practice. You do not have to use an inhaler. There is no extra charge for the test.

1 Have you ever been a regular smoker of tobacco ? YES ☐ NO ☐

2 Would you like a spirometry test ? YES ☐ NO ☐

If YES please answer the next question. If you answer NO please go to question 4

3 We would like to know some reasons why people have breathing tests.

Please mark any reasons that apply to you

Check up	YES ☐	NO ☐
Like to know my lung function	YES ☐	NO ☐
Worried about my lungs	YES ☐	NO ☐
Doctor asked me to have one	YES ☐	NO ☐
Saw a poster in the waiting room	YES ☐	NO ☐
Family or friend asked me to have one	YES ☐	NO ☐
Other reason (write here)		

4 We are interested in how people feel about spirometry testing and would like to know some reasons why they may not want to have a test.

Please mark any reasons that apply to you

I'm not interested in knowing	YES ☐	NO ☐
Result might worry me	YES ☐	NO ☐
Do not like having tests	YES ☐	NO ☐
I think my lungs are OK	YES ☐	NO ☐
Other reason (write here)		

Please turn ove

Please tell the receptionist NOW if you would like a test.

While you are waiting could you please answer some questions about yourself?

5 How old are you now? ☐ 6 Are you: Male ☐ Female ☐

7 What is your date of birth? Day/Month/Year ☐

8 When did you start smoking? Year ☐ Age ☐

9 How many cigarettes a day do (did) you usually smoke (on average)? ☐

0 Have you stopped smoking now? YES ☐ NO ☐

1 When did you quit? Year ☐ Age ☐

If you have quit please go to question 16
If you are still smoking please continue with question 12.

2 How long after waking do you have your first cigarette?

Less than 5 minutes ☐
6-30 minutes ☐
31-60 minutes ☐
More than 60 minutes ☐

3 Do you seriously intend to quit in the next 6 months? YES ☐ NO ☐

4 Do you seriously intend to quit within the next 30 days? YES ☐ NO ☐

5 Have you quit for more than 24 hours in the past 12 months? YES ☐ NO ☐

6 How do you rate your present state of health relative to others of your own age?

Mark with a X on the line the position of your rating

1=Much worse than average — 10=Much better than average

1 ——————————— 10

7 How likely is it that your lung health has been adversely affected by your cigarette smoking?

Mark with an X on the line the position of your rating

1=Not at all — 10=Very definitely

1 ——————————— 10

8 How important in your opinion are the benefits to stopping smoking for someone of your age?

Mark with an X on the line the position of your rating

1=Not at all important — 10=Very important

1 ——————————— 10

9 Do you get breathless with strenuous exercise? YES ☐ NO ☐ Pag

0 Do you get breathless when hurrying on the level or walking up a slight hill?
YES ☐ NO ☐

1 Are you slower than most people of your age walking on the level or do you have to stop for breath walking at your own pace on the level?
YES ☐ NO ☐

2 Do you have to stop for breath if you walk 100 metres or after a few minutes?
YES ☐ NO ☐

3 Are you being treated with any inhaler medicines at the moment?
YES ☐ NO ☐

Please write their names if you know them

[redacted]

4 Has your doctor diagnosed any lung condition?

Asthma	YES ☐	NO ☐
Chronic bronchitis	YES ☐	NO ☐
Emphysema	YES ☐	NO ☐
Chronic obstructive pulmonary disease COPD	YES ☐	NO ☐

Any other? [redacted]

Thank you for answering our questions.
Please write your name and details below.

Name: ☐ ID

Address: ☐
Number Street name Suburb Postcode

Home ph: ☐ Work ph: ☐

Mobile ph: ☐

If the nurse is here today you can be tested today. If you cannot wait or the nurse is not here, she will phone you to tell you when you can come. Some information about the study is attached, please read it while you wait.

Appendix 11: Questionnaire B for use in TN practices

MEASURING YOUR LUNG FUNCTION STUDY

that you have had a SPIROMETRY TEST could you please complete questionnaire. You can give it back to the receptionist or send it to the research team in the reply paid envelope. THANK YOU

: ID Date:

1 Marital status:
Single
Married or living with partner
Widowed or divorced

2 Postcode:

Date of birth: Day/Month/Year

3 What is the highest educational or vocational qualification that you have completed?

Mark one box only

- Grade 1 to 6
- Grade 7 to 9
- Grade 10 or 11
- Grade 12 or equivalent (eg HSC)
- Trade / Apprenticeship (eg. Hairdressing, electrician, plumbing)
- Certificate or diploma (eg. Child care, technician etc)
- University degree (eg. Batchelor)
- Higher university degree (eg. Graduate diploma, Masters, PhD)

4 How do you rate your present state of health relative to others of your own age?

Mark with a X on the line the position of your rating

1=Much worse than average — 10=Much better than average

1 ——— 10

5 How likely is it that your lung health has been adversely affected by your cigarette smoking?

Mark with an X on the line the position of your rating

1=Not at all — 10=Very definitely

1 ——— 10

6 How important in your opinion are the benefits to stopping smoking for someone of your age?

Mark with an X on the line the position of your rating

1=Not at all important — 10=Very important

1 ——— 10

age 1

Please turn over

7 Do you seriously intend to quit smoking in the next 6 months?

YES ☐ NO ☐

8 Do you seriously intend to quit smoking within the next 30 days?

YES ☐ NO ☐

9 How confident are you that you could stop smoking completely if you decided to:

Not confident ☐
A little bit confident ☐
Quite confident ☐
Very confident ☐

9 How much do the people among your close family or friends want you to stop smoking?

Not at all ☐
A little ☐
Quite a lot ☐
Very much ☐

The research team thanks you very much for your help with this study. We will send you a follow up letter in three months. If you have any questions you can phone the research nurse on 62267068

Appendix 12: Questionnaire C for use in TN practices

MEASURING YOUR LUNG FUNCTION STUDY

ree months ago you had a breathing test as part of a research study. No we would like to ask you some follow-up questions. Could you please complete this questionnaire. THANK YOU

Name: ID Date:

1 Have you completely stopped smoking now? NO Now GO to questi
YES

2 When did you quit? Date: Now GO to questi

3 Since your breathing test have you quit smoking for more than 24 hours?
YES NO

4 Since your breathing test how many times have you quit for more than 24 hours?
1 2 3 4 or more

5 How many cigarettes are you smoking each day (on average)?

6 Do you seriously intend to quit smoking in the next 6 months?
YES NO

7 Do you seriously intend to quit smoking within the next 30 days?
YES NO

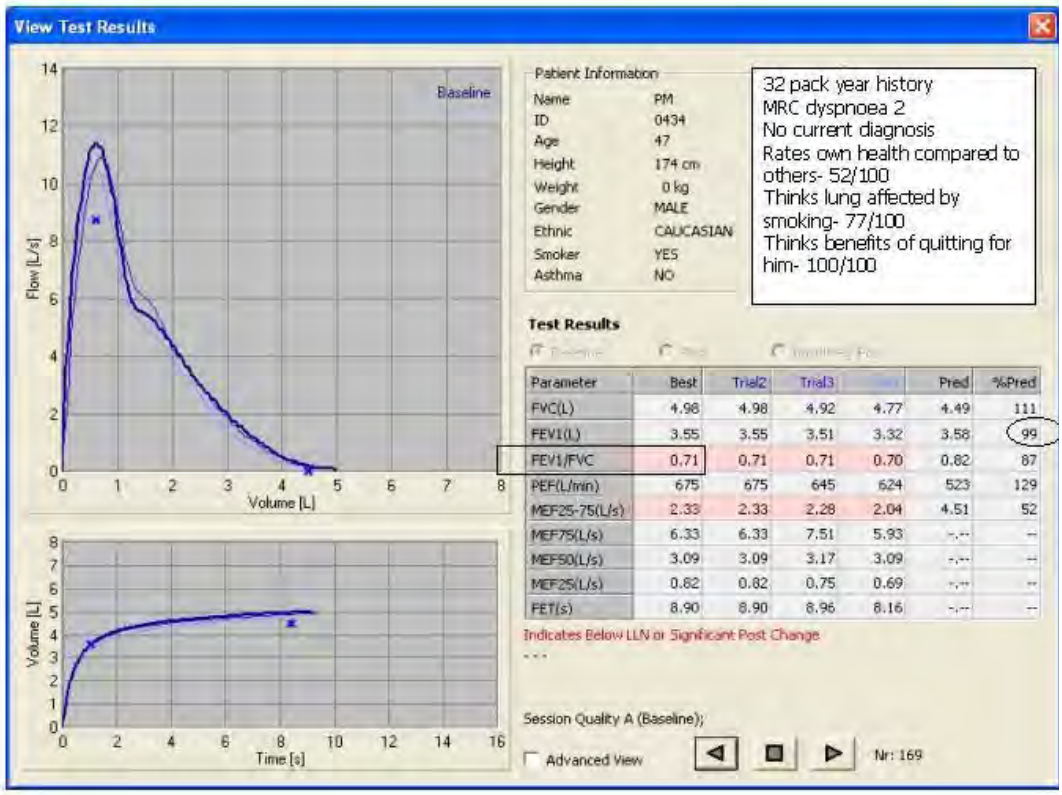
8 How do you rate your present state of health relative to others of your own age?
Mark with a X on the line the position of your rating
1=Much worse than average 10=Much better than average
1 10

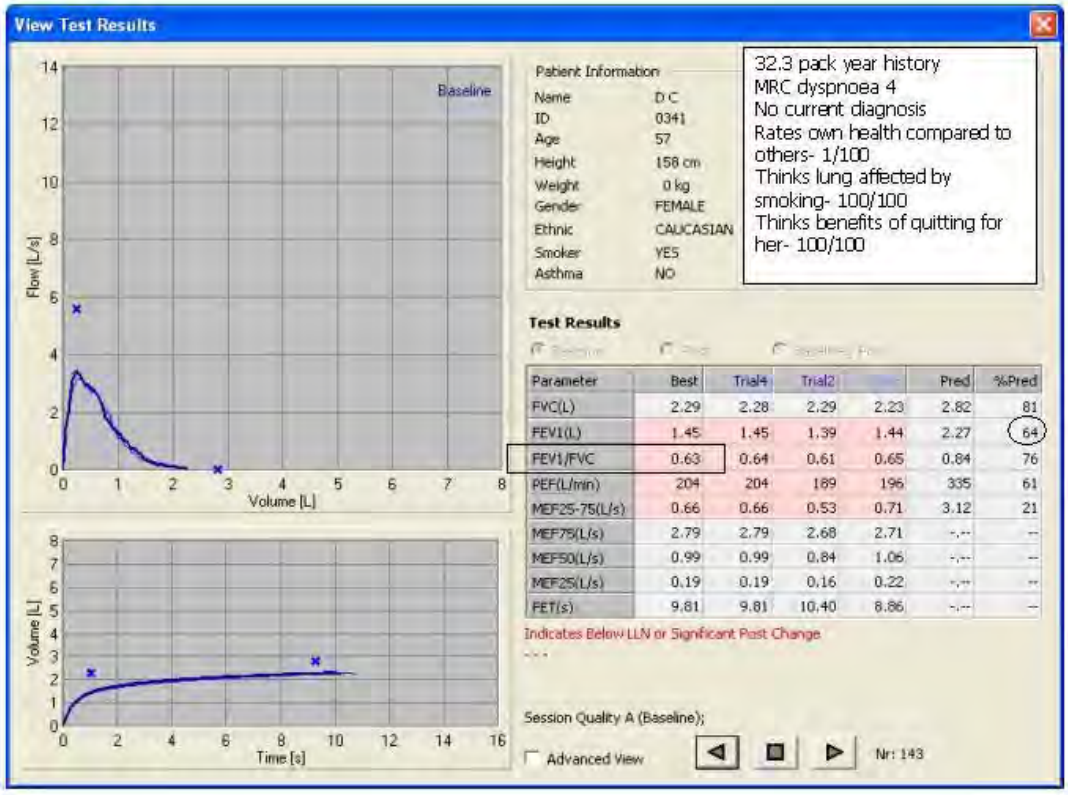
9 How likely is it that your lung health has been adversely affected by your cigarette smoking?
Mark with an X on the line the position of your rating
1=Not at all 10=Very definitely
1 10

10 How important in your opinion are the benefits to stopping smoking for someone of your age?
Mark with an X on the line the position of your rating
1=Not at all important 10=Very important
1 10

ase send this back in the envelope provided. If you have any questions y n phone the research nurse on 62267068. The research team thanks you very much for your help with this study.

Appendix 13: Two examples of spirometry results used in focus groups in practices





Appendix 14: Information and consent form for use in UC practices

Thank you for your help with this study into measuring lung function in general practice. This tells you what involves so you can decide whether to take part.

Purpose of the Study

We are investigating the best way to measure lung function (by blowing tests) in general practice. We want to use these tests to find out which smokers and ex-smokers over 35 years old have chronic obstructive pulmonary disease (emphysema and chronic bronchitis).

Who can take part

People who are patients of this general practice and whose GP thinks they should have their lung function measured.

What it involves

You have just had your lung function measured. We are now asking you to fill in a questionnaire asking about your smoking history, any existing lung problems you have and medications you are taking.

We would like permission to look at your notes in the surgery to assess any history of breathing problems you may have had and medications given.

Review of your notes

Confidentiality

The information we obtain for the study will remain confidential to the Research Doctors and Nurses. Records are kept locked in the Centre for Clinical Research at the Royal Hobart Hospital. Your anonymity is assured by our use of code numbers and not patient names. No findings which could identify you individually will be published. The information gathered will be stored for seven years as required by the University of Tasmania’s regulations and then destroyed.

Freedom to refuse or withdraw

Participation in the study is entirely voluntary. Should you decide not to enter this will not affect your future medical care in any way.

Contact Person

If you have any questions about the study please contact Dr Richard Wood-Baker on 62227068.

Ethical Considerations

The Southern Tasmania Health and Medical Human Research Ethics Committee has approved this study. If you have any concerns of an ethical nature or complaints about the manner in which the project is being conducted, you may contact a member of the Ethics Committee:

Chair – Dr Helen McArdle on 6222 8430

Executive Officer – Mrs Amanda McAully on 6226 2763 PTO

Consent Form

1. I have read and understood the information sheet for this study.
2. I understand that the study involves completing a questionnaire.
3. I am agreeable to the researchers viewing my medical records at this practice to extract information on respiratory disease and treatment.
4. I understand that the results of the study may not be of any direct benefit to my medical management.
5. I agree that research data gathered for the study may be published provided that I cannot be identified as a subject.
6. I have been provided with a telephone number for the researchers to ask any questions I may have.

Name: _____

Signature: _____ Date: _____

Appendix 15: Questionnaire A for use in UC practices

MEASURING YOUR LUNG FUNCTION STUDY

You have just had your lung function measured by SPIROMETRY. We are investigating the use of spirometry in general practice and would like to ask you to complete this questionnaire.

1 Have you ever been a regular smoker of tobacco ? YES ☐ NO ☐

2 How old are you now? ☐ 3 Are you: Male ☐ Female ☐

4 What is your date of birth? Day/Month/Year ☐

5 When did you start smoking? Year ☐ Age ☐

6 How many cigarettes a day do (did) you usually smoke (on average)? ☐

7 Have you stopped smoking now? NO ☐ **If you are still smoking go to question**

YES ☐

8 When did you quit? Year ☐ Age ☐

If you have quit go to question 13

9 How long after waking do you have your first cigarette?

Less than 5 minutes ☐
6-30 minutes ☐
31-60 minutes ☐
More than 60 minutes ☐

0 Do you seriously intend to quit in the next 6 months? YES ☐ NO ☐

1 Do you seriously intend to quit within the next 30 days? YES ☐ NO ☐

2 Have you quit for more than 24 hours in the past 12 months? YES ☐ NO ☐

3 Do you get breathless with strenuous exercise? YES ☐ NO ☐

Please turn over

Publications

1. Walters JA, Hansen E, Mudge P, Johns DP, Walters EH, Wood-Baker R. Barriers to the use of spirometry in general practice. *Aust Fam Physician* 2005;34(3):201-203
2. Walters J, Wood-Baker R, Walls J, Johns D. Stability of the EasyOne ultrasonic spirometer for use in general practice. *Respirology* 2006;11(3):306-310
3. Hansen E, Walters JAE, Wood-Baker R. Explaining chronic obstructive pulmonary disease (COPD): How middle aged and elderly people diagnosed with COPD describe the relationship between their illness and cigarette smoking. *Sociol Health Illn* 2007;29:1-20
4. Julia A. Walters, Emily C. Hansen, David P. Johns, E. Leigh Blizzard, E. Haydn Walters, Richard Wood-Baker. A mixed methods study to compare models of spirometry delivery in primary care for patients at risk of Chronic Obstructive Pulmonary Disease. *Thorax* 2007; accepted for publication 1st November 2007

Personal conference presentations

1. Walters J, Hansen E, Mudge P, Gartlan J, Wood-Baker R, Walters E. Factors influencing the diagnosis and management of Chronic Obstructive Pulmonary Disease (COPD) in two Tasmanian general practices. In: International Primary Care Respiratory Group World Conference; 2004; Melbourne, Australia.
2. Walters JAE, Hansen E, Mudge PR, Johns DP, Walters EH, Wood-Baker R. Barriers To The Use Of Spirometry In General Practice To Diagnose And Manage COPD. In: Thoracic Society Australia and New Zealand, Annual Scientific Meeting; 2005; Perth.
3. J Walters, E Hansen, P Mudge, J Gartlan, R Wood-Baker, EH Walters. Why is COPD not diagnosed earlier in primary care? In: GP & PHC Research Conference Tasmania; 2005; Launceston.
4. Knowledge of abnormal spirometry increases motivation to quit smoking (preliminary results). JAE Walters, DP Johns, E Hansen, J Gartlan, EH Walters, R Wood-Baker. In: Thoracic Society Australia and New Zealand, Annual Scientific Meeting; 2006; Canberra.
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Baker. In: Thoracic Society Australia and New Zealand, Annual Scientific Meeting; 2006; Canberra.

6. Stability of the EasyOne ultrasonic spirometer for use in general practice J A.E. Walters, Richard Wood-Baker, Justin Walls, David P. Johns. In: Thoracic Society Australia and New Zealand, Annual Scientific Meeting; 2006; Canberra.
7. The motivational effect of spirometry on smoking cessation. J. Walters, D.P Johns, E. Hansen, J.Gartlan, E.H. Walters, R.Wood-Baker. In: British Thoracic Society, Winter Meeting; 2006; London.